| 1  |     | Wednesday, 18 January 2012                               |
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| 2  | (9. | 30 am)   |
| 3  |     | DR JACK GILLON (continued)                               |
| 4  |     | Questions by MR GARDINER                                 |
| 5  | THE | CHAIRMAN: Good morning, Dr Gillon.                       |
| 6  |     | Mr Gardiner?   |
| 7  | MR  | GARDINER: Thank you, sir.                                |
| 8  |     | Good morning, Dr Gillon. Dr Gillon, you have             |
| 9  |     | previously appeared and given evidence to the Inquiry in |
| 10 |     | connection with statistics and B5, which was the topic   |
| 11 |     | about information to patients in the context of HIV, and |
| 12 |     | that was on the 24 June last year. At that time you      |
| 13 |     | talked about HIV look-back in Scotland. That's right,    |
| 14 |     | isn't it?  |
| 15 | A.  | That's correct, yes.                                     |
| 16 | Q.  | Today we are interested in Hepatitis C look-back and     |
| 17 |     | I think it would just be helpful if we could clarify     |
| 18 |     | a couple of terms with you because we get the impression |
| 19 |     | that the word "look-back" is used to cover many          |
| 20 |     | different exercises. Is that correct?                    |
| 21 | Α.  | That's correct and the big issue is really something     |
| 22 |     | that is called "targeted look-back", which starts from   |
| 23 |     | using a screening test on donors and finding a donor who |
| 24 |     | is carrying the relevant infection and that then         |
| 25 |     | triggers the targeted look-back to the previous          |

1 donations in an attempt to find the recipients.

2 Q. Yes.

A. You can do it the other way round, which we coined the 3 term "reverse look-back" for. The North Americans refer 4 to that as "trace-back", where a patient presents to 5 a clinician, very often it would be a hepatologist, with 6 7 signs of liver disease, discovered to have Hepatitis C in this instance, and the clinician, if they remember to 8 9 do so, which I regret to say isn't always the case, 10 thinks to inform the blood bank that they have such a patient who has a history of transfusion. 11

12 We would then seek, first of all, details of that 13 transfusion episode, all of the units that were 14 transfused; we would identify the donors and carry out 15 investigations to see if we could find a donor who had 16 transmitted infection.

That's what we call a "reverse look-back", which is something that we had done long before there was a screening test. So you will see that that's not dependent on a screening test being available or indeed any kind of test.

22 So prior to 1990, we would have been told that there 23 was a patient with non-A non-B Hepatitis and we would 24 have identified the donors, and what we would have to do 25 in those days, prior to the test, was haul those donors

1 in, tell them there had been a problem with a patient 2 who had received their blood and that we needed to look 3 into that, and obviously that was (a) onerous, because you had to get all of the donors back, and sometimes it 4 would be hundreds but more often it would be a smaller 5 number. You would take a full history, see if you could 6 7 identify a risk factor, do liver function tests and the 8 end result of that was often quite inconclusive.

9 So often those donors were left in limbo and we were 10 left in limbo to some extent as well. So when a test came along, there was a very obvious area to go for to 11 12 try and sort these out faster and with better resolution 13 for the donors and that, I think, was what Dr Cash was 14 referring to when he wrote to Dr Gunson asking if we 15 could just get ahead and do that while discussing the targeted look-back, the big thing -- the numerically big 16 17 thing was targeted look-back.

18 Q. You were here for Professor Cash's evidence yesterday?19 A. I was, yes.

Q. And you think that the early correspondence, talking about around about May 1990, between Professor Cash and Dr Gunson -- what they were talking about was reverse or trace look-back?

A. I think they were dealing with that as a separate issueand could this be sort of fast tracked and just done.

1 I'm not sure it was particularly well resolved but 2 I suspect that those of us on the ground were doing it 3 on a more informal basis, probably at the same time as that correspondence was going on, because obviously if 4 you had such a case and you knew that Eddie Follett 5 6 could test all those donor samples, you would do that. 7 Q. Yes. I can't remember if there was any specific instances but 8 Α. 9 it would have been crazy not to. 10 Just to show an example of that correspondence, could we Ο. have a look at [SNB0045010]? It's a letter of 11 12 21 May 1990 from Dr Gunson to Professor Cash. The 13 heading is "HIV look-back", and you say: "I'm not sure that our RTCs will have access to 14 15 anti-HCV test material." So they are clearly thinking about Hepatitis C as 16 17 well: "I think that it may be worthwhile to carry out the 18 19 usual investigations when a transfusion-associated NANBH case is reported and to ensure that a library sample of 20 serum is retained from each donor seen." 21 22 What do you think is being discussed there exactly? 23 I think that is the answer to Professor Cash's letter Α. 24 raising this subject, and I would take that as implying 25 that if the test was available we should just get on

1 and do it in that situation.

| 2  | THE | CHAIRMAN: Mr Gardiner, from the context I think that   |
|----|-----|--|
| 3  |     | "HIV" should be "HCV". I think that's right.           |
| 4  | A.  | Yes.   |
| 5  | MR  | GARDINER: So is that a discussion of reverse or trace  |
| 6  |     | look-back?   |
| 7  | Α.  | That is only about reverse look-back.                  |
| 8  | Q.  | So that is, as you explain, distinct from targeted     |
| 9  |     | look-back, when you are going back to the previous     |
| 10 |     | donations and seeing what has been done with those     |
| 11 |     | donations, who has received blood components made from |
| 12 |     | those donations. Is that right?                        |
| 13 | A.  | Yes, and that could only happen once routine screening |
| 14 |     | across the donor population was introduced.            |
| 15 | Q.  | Yes, there is a kind of look-back maybe I'm using the  |
| 16 |     | wrong word but this is a process whereby you would go  |
| 17 |     | back to other donations and make sure that, if they    |
| 18 |     | hadn't been used, they weren't going to be used,       |
| 19 |     | quarantined if you like?                               |
| 20 | Α.  | Yes, that would be part of the targeted look-back. So  |
| 21 |     | that if there were for instance, in a plasma donor,    |
| 22 |     | there may have been material from the previous month   |
| 23 |     | still in stock FFP or whatever. One of the first       |
| 24 |     | things you would do when you identify a seropositive   |
| 25 |     | donor and again this is predicated on routine          |

1 screening because you are not going to know this 2 otherwise -- the first thing you do is quarantine 3 anything that might still be transfusable, and if that's out of blood banks and peripheral hospitals, you would 4 tell them and they would get on with that. 5 Would that not be done if you are not doing targeted 6 Ο. 7 look-back, if you like? 8 No, it wouldn't be relevant there because your starting Α. 9 point is the patient and quite often the transfusion 10 would have been several years earlier, so it would be a clinician, say, in 1989 saying, "We have got a non-A 11 12 non-B", the person was transfused in 1986, say. So you 13 are trying to identify the donors of all those donations 14 that patient got in 1986. 15 Again, one of the first things you would do having identified those people is look at the donor record, and 16 17 if one of them gave and there was still material in 18 stock, you would take that out of circulation. So you 19 would make whatever we had safe in that sense. 20 Q. Thank you. THE CHAIRMAN: Mr Gunson refers here to "the usual 21 22 investigations", which would appear to distinguish what 23 he is talking about from the setting up of a new system 24 in some way.

25 A. Yes, and that's what I described. You would have to

1 look at the donors individually and decide whether you 2 could identify a culprit, if you like. And I suspect that different transfusion services did slightly 3 different things and even within Scotland we probably 4 had variations on a theme, but broadly speaking we did 5 6 the same thing. 7 MR GARDINER: Yes. I think we can put that away now, thank 8 you. 9 You were asked to provide a statement for this topic 10 and if we could have a look at that. That's [PEN0180410]. You repeat the questions that you were 11 12 asked. 13 A. Yes. Q. So the first question was: 14 15 "What was Dr Gillon's involvement in the look-back 16 exercise." 17 Could you just tell us about that? 18 What I set out there is, broadly speaking, why it became Α. 19 my responsibility in Southeast Scotland to deal with 20 look-back, and initially that was more or less because 21 of HIV testing, which began very shortly after I was 22 appointed, and where targeted look-back was agreed 23 across the UK to be something that we would do right 24 from the start of testing. 25 Of course, I had also -- as soon as I took up my

post -- inherited the files on one or two of the historical look-backs which -- indeed, some of them were HIV-related, where clinicians had identified a case and we had done the reverse look-back thing. But up until that point there was no real targeted look-back going on.

7 But once HIV was agreed to be an appropriate case for look-back, we did it across the country routinely 8 9 and I did the Southeast Scotland bit of that. So when 10 I was asked in 1990 to draw up some documents about counselling and management of donors and so on by 11 12 Professor Cash, as we heard yesterday, one of the things 13 we addressed in that working party was indeed look-back 14 and we came to, as I recall, a unanimous decision that 15 we should do that and included it in that report, which 16 went to the directors.

Q. Yes. Let's have look at the letter that you refer to at
the bottom of the page there, which is [SNB0055023].
This is a letter of 21 June asking you, because it is
a high priority, to produce operational guidelines for
BTS doctors in the context of counselling anti-HCV
confirmed positive donors.

23 By this stage what experience had you had of that 24 kind of thing?

25 A. Well, of course the numbers of donors found positive

1 with HIV wasn't huge but there were some regular donors 2 among them. And right from the start -- in fact, when you introduce a new test, it's likely to be at the start 3 that you are going to find these things that have 4 accumulated over the previous, well, two or three years 5 in the case of HIV, simply because you are dealing with 6 7 regular donors who are by and large giving every six 8 months or so. So within your first six months of 9 testing, you are going to find a large proportion of the 10 regular donors and you see that in the charts when we follow the figures, that you get a hump at the start. 11

12 So, yes, we had had to go through that process and 13 identify patients who had been infected by prior 14 donations and we had experience of doing that.

We hadn't had a standardised, national set of documentation for doing that but I'm absolutely sure we were all doing exactly the same thing.

18 Q. So you had been involved yourself in counselling in the 19 context of HIV?

A. Yes, yes, I had -- it was shortly after I took up my post in 1985 in the run up to HIV testing, I had spent -- I can't remember if it was a week or two weeks at St Mary's in London with Dr Tony Pinching, who had the biggest cohort of HIV positive patients in the country, and visited the GUM clinic and discussed with

him and microbiologists and so on, and one of our doctors, the sessional medical doctor in the centre, Dr Jan Davidson, did the same thing, she went down to a counselling course they ran for HIV testing, and between us we dealt with the counselling of HIV positive donors.

7 So we had experience of the sort of issues that 8 would crop up when you are dealing with the donor and 9 indeed, in dealing with the patients who came through 10 the look-back -- because by and large -- I guess I would 11 have done all of that myself in the case of HIV because 12 the numbers were small. So we had quite lot of 13 experience there.

Q. Just before we move away from it, the last time you were here, you told us that from 1985, when HIV screening came in, SNBTS retained samples of blood which had been donated. That's right, isn't it?

18 Yes. The very first archive started in the southeast in Α. 19 the middle of 1984 and by, I think, early 1986, all of the Scottish centres were laying down a sample of every 20 21 donation, which has continued to this day, and all of those samples are still there, except the ones that have 22 23 all been used up in retrospective testing. But by and 24 large they are all there, very many millions of samples. 25 PROFESSOR JAMES: "Laying down" sounds like the lessons you

1 must have had from the Scotch whisky industry. 2 A. In the famous claret links of Edinburgh indeed as well, 3 yes, it always pays off. PROFESSOR JAMES: Quite. Sorry. 4 MR GARDINER: But you had had experience of counselling in 5 6 the HIV context and experience of HIV look-back; do you 7 think that was why you were asked by Professor Cash to 8 chair this group? 9 Α. I quess it must have been, yes. And the other members -- what experience did they have 10 Ο. of that kind of thing? 11 12 If I remember correctly, it was George Galea, Α. 13 Bob Crawford and Jan Davidson. Was that everyone? 14 Q. Yes. 15 Bob Crawford and George Galea were my exact Α. counterparts. Dr Crawford in the west, Dr Galea in 16 17 Aberdeen at that stage in the early days, but by the 18 time HIV came along, I think he was probably still in 19 Aberdeen as donor consultant in Aberdeen at that stage. 20 Jan Davidson was the doctor I mentioned who had done 21 HIV counselling training and had a lot of experience in dealing with donors in this situation. 22 23 Q. Yes. How did you set about that task? 24 Α. Well, I think we were given a pretty short deadline, 25 so -- I can't remember. I don't have any notes of those

meetings unfortunately but I would have guessed we met within a month or so.

Just before dealing with that, I think probably the other reason John Cash asked me to do that was from my background in gastroenterology and indeed, after taking up my post in BTS, I continued with an interest in gastroenterology with a weekly clinic. So I was still kind of plugged into what was going on there.

9 Q. Yes.

10 But we had to get this moving quickly. It was a small Α. group. We would have met, I would guess, at least twice 11 12 before we pulled together a draft, and it would have 13 started with throwing around the ideas -- what comes up when you talk to donors? -- and that's probably where 14 15 the question arose -- what about previous donations? Q. Okay. So if we have a look at [SNB0045074], this is 16 17 your letter to Professor Cash, 20 September 1990, 18 sending the first draft of the document.

19 A. I see in the previous letter the deadline was something
20 like 14 August and that was in the middle of June.
21 I don't think that was very realistic and indeed, we
22 didn't meet that deadline. So September is not bad,
23 I don't think.

Q. That's very quick. I think if we look at [SNB0053647],
and if we could just go to 3656, we see at the bottom of

1 the page the date is 12 September 1990. So that looks 2 like the draft that was sent with the letter that we 3 have just seen. A. Yes, there obviously was an earlier draft because in the 4 previous letter I see that I had sent it to 5 6 Harold Gunson by that time. So we must have regarded 7 this as a fairly final sort of draft. 8 Q. Okay. 9 A. More in optimism than expectation, probably. 10 Q. Right, okay. Could we just go back to the first page, 3647? There we see that it's the report for the 11 12 National Medical Director. So you considered that it 13 was Professor Cash that was asking you to do this? 14 A. Yes -- well, yes, he had written to me as an individual. 15 Ο. Yes. 16 A. Yes. 17 Q. So it wasn't the Medical and Scientific Committee that 18 was asking you to do this? 19 A. I would probably have known that they would have debated 20 this, I suspect, although I wasn't a member of that 21 committee. Q. Yes. How much was generally known about the discussions 22 23 of the MSC -- by yourself, for example? 24 Α. I think Brian McClelland sent all of us, as Consultants 25 in southeast, a copy of the minutes of all the meetings

| 1  |    | that weren't in some way regarded as confidential, as    |
|----|----|--|
| 2  |    | hyperconfidential. So the directors' meeting, the        |
| 3  |    | I don't think we saw the coordinating group meetings but |
| 4  |    | he would have sent us the directors' meetings minutes    |
| 5  |    | and the minutes of the MSC. So yes, we probably had      |
| 6  |    | seen that.   |
| 7  | Q. | Did you generally read the minutes of the MSC that were  |
| 8  |    | sent?  |
| 9  | A. | Oh, yes.   |
| 10 | Q. | So you felt that you were up-to-date with the            |
| 11 |    | discussions at the MSC meetings?                         |
| 12 | A. | Yes, I think so, yes.                                    |
| 13 | Q. | Okay. Could we just go to the next page? Who drafted     |
| 14 |    | this document?   |
| 15 | A. | I'm pretty sure I drafted it.                            |
| 16 | Q. | Yes.   |
| 17 | A. | In fact I think I initialed it at the bottom.            |
| 18 | Q. | Right. So you would have drafted it and circulated it    |
| 19 |    | to the other members of the working party?               |
| 20 | A. | Yes.   |
| 21 | Q. | Yes. Would they have had an opportunity to suggest       |
| 22 |    | revisals?  |
| 23 | A. | Yes, certainty.  |
| 24 | Q. | Do you remember if that's what happened?                 |
| 25 | A. | I'm sure that's what happened. I can't remember how      |
|    |    |  |

1 much revision went on in that short time period but by
2 and large we were in broad agreement.

Q. Just to understand, what was the knowledge that you were drawing on to produce this? Obviously you had your own experience, all of your own experience, but did you look further afield to other research?

7 Α. Yes, there was already a fairly extensive published body of work on HIV look-back, and we knew the difficulties 8 9 involved. I remember that Herb Peterkin's group in 10 San Francisco published about their efforts and they, of course, had a massive problem with HIV and they tried 11 12 very hard to find the recipients of previous donations 13 with very limited success. Even -- they called it an "extended look-back". They went to great lengths to try 14 15 and find people, through public health departments and just turning over every stone they could to find people. 16 17 And the outcome was still disappointing in terms of the number of people you could identify compared with the 18 19 amount of effort they had put in. We knew that. We 20 knew that it wasn't an easy process. We knew from our 21 own experience it was going to be difficult. 22 And in terms of the other things that you were Q. 23 considering, which was counselling and so on, again, 24 what did you have reference to to help you draft the

25 document?

1 Well, we already, I think, were starting to get a feel Α. 2 for how the testing would turn out in terms of numbers. And at that time in the middle of 1990, it was all based 3 on first generation testing, which had of course been 4 routinely introduced in several countries by that time. 5 I think by then probably Eddie Follett and Brian Dow had 6 7 had first generation kits to look at and had looked at 8 some retrospective samples and probably done some donor 9 samples as well. I can't remember the exact dates of 10 that but by then we knew that if we were going to be doing this on the basis of a first generation test, the 11 12 numbers were daunting.

13 Initially it was looking something like 14 0.5/0.6 per cent in Scottish donors who would come up 15 positive in the first generation test, and we translated that into the sort of numbers that that would provide, 16 17 which would be around ten a day in Scotland. We used to 18 work on the assumption that we took about 1,000 19 donations a day on weekdays. And we were looking at 20 around ten a day across Scotland, which was pretty 21 substantial and we knew that to do that -- to do a look-back on those numbers, we would need extra 22 23 resource.

24 So that was one of the reasons why I think we felt 25 we should flag it up early saying, "In principle, we

1 think this needs to be done". I don't think we put 2 anything about the need for resources in this particular document. I don't think that would have been 3 4 appropriate. Q. So at this time, September 1990, you were proceeding on 5 6 the basis that any targeted look-back would involve the 7 first generation test which was giving you these really 8 quite high numbers? 9 Α. Yes, that's right. 10 Yes, okay. And just to observe, Dr Gillon, that Ο. ultimately, when look-back was introduced in 1995, a lot 11 12 of what's in this document here was actually used. Is 13 that right? 14 Yes, yes, it was the basis for the UK documentation. Α. 15 Yes. Could you indicate which bits were ultimately Ο. 16 used? We are looking at the introduction at the moment. 17 I think if we go to 3651, this is the section which 18 deals with background information for SNBTS medical 19 officers counselling anti-HCV-positive donors. Was this 20 section used in the final look-back documentation? 21 A. I think the final documentation looked pretty like this. 22 Thinking back to the letter that came from the chief 23 medical officer. But of course, that was four or five 24 years later. The figures would have been updated, there 25 was a little bit more known about natural history and so

1 on, and things like sexual transmission. So it was 2 certainly completely revised at that stage and that was 3 done by the working party, which was set up in 1995. Q. Okay, we will come to look at that. What were you doing 4 in this particular section of the document? What was 5 6 the purpose? 7 Α. This was very much aimed at the doctors who would have to sit down with a donor and say, "We have got this 8 9 blood test result and here is what it means." It was 10 specifically about educating the donor doctors. About the nature of the disease? 11 Q. 12 The nature of the disease, what it would mean for an Α. 13 individual, what the natural history was, so far as we 14 knew at that stage, and what would need to happen to 15 that individual beyond that. 16 What knowledge did you draw on to draft this particular Q. 17 bit of the document? Did you have reference to research 18 papers? 19 Yes, and, of course, we all followed avidly the research Α. 20 output from across the world on non-A non-B Hepatitis. 21 So, I mean, it was a big issue from the time -- well, 22 before I came into blood transfusion, but it was a very 23 hot issue when I came in and was part of the reason why 24 I was sent off to the United States for three months 25 before I took up my post, to look at HIV and non-A non-B

1 specifically and talk to the experts.

2 So we had followed that story and we had our own 3 experience. We had, as we heard earlier, a lot of research effort going into that in both Edinburgh and 4 Glasgow, and of course at conferences that we all 5 6 attended year in, year out. It was a big topic. 7 Q. Could you remind us about your visit to America for that 8 three-month period? 9 Α. Yes, basically I spent it in Kansas City where there was 10 a blood centre which was modelled -- well, not modelled but coincidentally, I suppose, along the lines of what 11 12 we had in Scotland and about the same size as the 13 Edinburgh centre in fact, with a clinician -- a director who was a clinician -- actually a haemophilia doctor --14 15 who was very interested in keeping up clinical links 16 between blood transfusion and the clinical 17 hospital-based transfusion practice.

18 So that was partly to educate me in the sort of 19 haematological aspects of blood transfusion, which I had 20 only very limited knowledge of as a gastroenterologist, 21 but for the last month I travelled extensively, mainly 22 in the eastern seaboard, Washington DC, and other points 23 east, including the Centre for Disease Control in 24 Atlanta, where there was a lot of research going on into non-A non-B Hepatitis, and in the course of that I met 25

with people like Harvey Alter, I suppose the best known
 expert in this area.

3 Q. Yes. Was there anything that you felt that you learned 4 during that period that you applied to the composition 5 of this document?

A. Not particularly. I think -- when I was there was
almost exactly when they introduced HIV testing and
there was no controversy about doing HIV look-back,
which I saw first hand in the States and reported back
to John Cash, and there was no controversy in this
country about introducing that either.

12 Q. Yes. I see. Okay. Could we have a look at 3654 in 13 this document. This is headed "Informing the donor". 14 Could you explain what this section is about?

15 This is an attempt to be very practical. These were the Α. 16 early days of SOPs and I noted yesterday that this quite 17 rapidly became an SOP -- a standard operating procedure. 18 In fact we were just trying to describe in very clear 19 terms what needed to be done to make this work, so that 20 doctors who didn't have much experience of this would be 21 able to do it basically, with very little in the way of additional training. 22

Q. Yes. Was it envisaged that this section would be given
to a patient as a way of explaining the situation or is
it just a way of explaining to the counselling doctor

1 the information he should be imparting?

2 I think it's the latter entirely. We would never have Α. handed this over to a donor or indeed a patient. 3 Q. Yes. Okay. Could we go to 3656? We see the second 4 question in that page is "What about my previous 5 6 donations?" It says: 7 "The recipients of previous donations will be traced 8 and their consultants or GPs informed. We hope to 9 obtain results of any tests carried out." 10 Just to be clear, what's that a reference to? That is the reference to look-back, to targeted 11 Α. 12 look-back. And I think partly in response to your 13 previous question, this was partly angled towards 14 something we would produce to give to the donor and did 15 produce on the basis of this. I can't remember if it 16 was in question and answer format and I think it may 17 well have been but you can see that the tone changes 18 after the second sentence to giving background for the 19 doctor, really. Saying, "However, it may cause distress 20 to the donor to discuss this in any detail," and 21 a recommendation about how to approach it. So it was 22 kind of looking both ways, I suppose. 23 Yes. So we can just put that away now. Do you remember Q. 24 what happened next in terms of the evolution of this

25 situation?

1 A. As I recall, John Cash wrote back saying that this was 2 very well received and the Scottish directors had accepted it and that he would be discussing it with 3 colleagues down south and sharing it with them, as we 4 had already agreed and Harold Gunson had seen it, of 5 6 course. 7 I think before that it was discussed at an MSC meeting. Q. Yes, I think that's right. I think I attended to speak, 8 Α. 9 yes. Could we just have a look at the minutes of that? 10 Ο. It's [SNB0095513]. If we just look on the first page there, 11 12 6 November 1990, so this is just a few weeks after your 13 letter, and Professor Cash, Dr Mitchell, Dr McClelland -- could we go to 5516? At the bottom of 14 15 the page, paragraph 5(ii): 16 "Dr Gillon's report, which had been previously 17 circulated, was discussed. "Dr Mitchell pointed out that Dr Gunson was anxious 18 19 to take this Gillon document to the national advisory 20 committee in the near future." 21 Could we go over the page? We see, third paragraph 22 down: 23 "The committee concluded that a draft standard 24 operating procedure based on this report should be 25 prepared by Dr Gillon by 30 November 1990 and submitted

1 to the members of the MSC for their consideration. This 2 he agreed to do." Do you think that you were at that meeting or have 3 you got a memory of being there? 4 A. The one that these minutes --5 Ο. Yes? 6 7 Α. -- refer to? Yes, I'm sure I was there. 8 Do you have any memory of the discussions around about Q. 9 your document? 10 A. I can't say that I do. Q. No. If we could go to 5519, we see point 10, "HCV 11 12 look-back": 13 "After discussion it was agreed that Professor Cash 14 should write to the chairman of the DOH advisory 15 committee on the virus safety of blood asking that 16 careful consideration be given to the matter of HCV 17 look-back of recipients of previous donations." "HCV look-back of recipients of previous donations", 18 19 would you say that that's referring to targeted 20 look-back? 21 A. Yes. Q. Clearly, your draft has raised the question of what is 22 the policy about targeted look-back? 23 24 A. Yes, and I can't remember any details about the 25 discussion. I'm sure there would have been fairly

1 vigorous discussion about the potential difficulties and 2 whether we would need new resources and so on, but I think the outcome is clear, that it was accepted that 3 it should go forward. 4 Q. Yes. Targeted look-back --5 Targeted look-back. 6 Α. 7 Q. Yes. So your recollection is that at that stage the MSC 8 had a positive attitude to targeted look-back, or was it 9 stronger than that? 10 I don't think it was stronger than positive. And there Α. were some people who had reservations about it, I'm 11 12 sure, particularly in the west, where the problem 13 numerically was always going to be greater. 14 Yes. Can you remember if that was discussed? Q. 15 I'm sure it was, yes. I know that even Bob Crawford, Α. 16 who was on our group, was very leery of this because of 17 the amount of work it would create, but the answer to 18 that was clearly more resources. 19 Q. So the concern was that necessarily there would have to 20 be a lot of work to go ahead with targeted look-back and 21 the question was: well, how is that going to be done, 22 will there be resources to do it? Is that the 23 situation? 24 A. Yes, and I do remember that we discussed this when I was 25 talking about ten a day in Scotland. We all knew that

1 if that was the outcome, that we were using first 2 generation testing, we would nearly all have needed some at least secretarial help, if nothing else. So we 3 weren't talking about a fortune but we knew we would 4 need some help to do it. 5 Q. Would you just bear with me? (Pause) 6 7 Could we go back to 5517? We can see there that you 8 are being asked to redraft the document that has been 9 produced but you are not being asked to remove the 10 question that we looked at, the question that raises the issue of targeted look-back? 11 12 A. No, not at that stage, certainly not. 13 Could we go to [SNB0018779]? I'm right in thinking that Q. 14 your report went through several drafts? 15 Yes, it did. I can't remember how many. I think there Α. was at least a fourth draft. 16 17 If we look at 8789, we will see that at the bottom of Ο. 18 the page, please, that this draft is dated 19 23 November 1990. Can you remember what the difference 20 between the one that was presented to the committee and 21 this one was? 22 A. I am afraid I can't. I don't think I had been asked to 23 change it at that stage. I see it says "TTD/39" at the 24 bottom. Whether this was one that was to be discussed 25 by that committee, the advisory committee on TTD,

1 I don't know. But I don't think I had been asked to 2 amend it at that stage. Q. So "TTD" you think might be a reference to the Advisory 3 Committee on Transfusion Transmitted Infections? 4 5 A. I would think so, yes. O. Yes. 6 7 THE CHAIRMAN: "TTD/39", would that tend to indicate it was 8 a reference number to their agenda? 9 I would think so, yes. It's the only thing I can think Α. 10 of. It's not a number that I would have used or recognised. 11 12 MR GARDINER: Okay, thank you. Could we go to 8788? We can 13 see that that question, the targeted look-back question, is still there. 14 15 A. Yes, and the wording is still the same, yes. Q. Okay. If we could now go to [SNB001 --16 17 THE CHAIRMAN: Sorry, just before you do, if we could go 18 back, please, to the next page, where we were, something 19 has been scored out. I wonder if you can cast any light 20 on that. If one looks at the question as it was, does 21 that reflect your document and then someone has scored 22 something out? 23 A. It's someone other than me who has done that. I presume 24 this was part of the papers for a TTD meeting and that 25 was somebody saying, "I want this taken out "'.

1 THE CHAIRMAN: "I want this out", yes.

2 MR GARDINER: I think the next draft we see it's still 3 there. PROFESSOR JAMES: But there was a discussion, we heard 4 yesterday, and it ultimately was scored out. This 5 6 particular item about informing the dentists was 7 ultimately scored out, I believe. 8 MR GARDINER: Yes, thank you. So if we could go to the next 9 draft, which is [SNB0018803], we see that this one is dated February 1991 and we see "TTD 11/91", and if we 10 could go to 8809, please -- sorry, just before we go, we 11 12 notice there that it's draft number 4. 13 A. Yes. Q. This is the final one; is that right? 14 15 It's the last one that I have seen. I don't remember Α. seeing one that says "final draft" or anything like 16 17 that. 18 Yes. The Inquiry has not been able to find any draft Q. 19 after this one. A. I haven't either. 20 21 THE CHAIRMAN: What's the reference at the bottom of that 22 page Mr Gardiner? "TTD"? 23 MR GARDINER: Yes. Could we now go to 8809, please? If we 24 look at the bottom of the page, we see the question, the 25 targeted look-back question, and if we could go to the

1 top of the page, we see that that's on page 9. Are you 2 able to remember what alterations, if any, were made to this draft from the November draft? 3 A. I am afraid I don't. In fact I'm pretty sure I had 4 heard from John Cash by then that the committee --5 6 whether it was this one or MSBT, I can't remember -- was 7 recommending that look-back shouldn't be done. But 8 I can't remember if I had been asked to amend it by that 9 stage. Okay. The next letter I'm going to show you might help 10 Ο. with that. It's [SNB0051689]. It's a letter to you 11 12 from Professor Cash: 13 "I have pleasure in informing you that the Medical 14 and Scientific Committee examined your final draft 15 document at its meeting on 19 February 1991 and found it to be excellent. 16 17 "The Committee agrees to the proposal that the latter pages be used nationally as guidelines in leaflet 18 19 form within the RTCs. 20 "It was noted, however, that in the light of 21 national events with regard to the implementation of 22 'look-back', that the last question on page 9, ie 'What 23 about my previous donations', and the answer should be 24 omitted from the final document." 25 Dr Gillon, when you received that letter, what did

| 1  |    | you understand by the phrase "in light of national       |
|----|----|--|
| 2  |    | events"?   |
| 3  | Α. | I think at the time I had no idea. I think I must have   |
| 4  |    | understood that there was disagreement down south about  |
| 5  |    | doing it and that's the only interpretation I can make   |
| 6  |    | of "national events" in that context.                    |
| 7  | Q. | Was your understanding of why this question was going to |
| 8  |    | be taken out enhanced by your discussions with           |
| 9  |    | Professor Cash around about this time?                   |
| 10 | Α. | No, I don't recall ever being given an explanation.      |
| 11 |    | I think it would have been understood to be largely      |
| 12 |    | a resource issue but I know there were people in         |
| 13 |    | London who disagreed with it in ethical terms, if you    |
| 14 |    | like, but largely it was a resource issue, I think.      |
| 15 | Q. | What would be the basis for that disagreement? What was  |
| 16 |    | your understanding?                                      |
| 17 | A. | Well, we heard yesterday from Professor Cash about the   |
| 18 |    | doubts about doing this when you couldn't offer anything |
| 19 |    | in the way of specific treatment, although, as I saw in  |
| 20 |    | one of the drafts of the document there, we do refer to  |
| 21 |    | interferon treatment in that background information as   |
| 22 |    | having been done both in the context of non-A non-B      |
| 23 |    | Hepatitis, and the studies where the HCV test was used   |
| 24 |    | initially to confirm that it wasn't HCV they were        |
| 25 |    | dealing with, and we saw yesterday the paper from Makris |

1 and others in the north of England and haemophilia 2 patients. So there was already a body of evidence that interferon might be used in this condition and might 3 give some beneficial results. But if there was an 4 ethical objection to it, it was usually couched in terms 5 of no treatment being available. 6 7 Yes. So in draft number 4, you referred to interferon Q. treatment? 8 9 Α. Yes. Yes. Could we go back to that, please, at page 2 of 10 Ο. [SNB0018803]? Are you able to point us to the section? 11 12 I think, if we could look for page 9 again, I think Α. 13 I caught sight of it when you went to the top of page 9. 14 That's 8809. Oh, yes. Yes, the first paragraph? Q. 15 Yes, so it will have started over the page. Α. So could we go to the page before? So the question is: 16 Q. "Will I die of this?" 17 18 And the sentence about interferon starts on the page 19 before: 20 "It is felt by some hepatologists that very few 21 cases of serious liver disease due to Hepatitis C occur in the community. So for most people this is an 22 23 incidental finding unlikely to cause serious disease or 24 symptoms of any kind." Going over the page: 25

1 "Progressive chronic Hepatitis C has been treated 2 successfully with interferon, and though this treatment is at present experimental, it holds out considerable 3 promise for the future." 4 So that's the reference in the document? 5 That's the reference. 6 Α. 7 Q. Yes, thank you. Dr Gillon, what was your reaction when you received that letter from Professor Cash 8 9 in March 1991? I was pretty appalled. I felt strongly that we should 10 Α. be doing look-back right from the start. Even if there 11 12 was difficulty in coping with the numbers, we should at 13 least make the attempt. And at the very least we should -- if we felt it was ethically desirable to do 14 15 that -- and my take on what everybody had been saying at the meetings was that there was no serious ethical 16 17 difficulty, in fact the ethical thing to do was to do 18 what we had done for HIV, and that if that was the case, 19 it was our job as doctors to say, "We are going to do 20 this," and if we couldn't do it because of resources, we should ask for resources. 21 22 Q. Yes. Was the reason that you were appalled because you 23 felt, from an ethical point of view, it was the right 24 thing to do? A. Yes, I was confident of that. I was willing to debate 25

1 that with anybody.

| 2  | Q. | Yes. Thank you. Did you have an opportunity to debate    |
|----|----|--|
| 3  |    | that with Professor Cash?                                |
| 4  | A. | Not that I recall, other than being in the meetings like |
| 5  |    | the MSC, where, as I say, it seemed to be accepted that  |
| 6  |    | we should be doing it. It came as a bit of a surprise    |
| 7  |    | that Scotland was not going to be doing this.            |
| 8  | Q. | If we could go back to your statement, please, could we  |
| 9  |    | go to the second page, 0411? So the second paragraph,    |
| 10 |    | you have just referred to the letter of 12 March 1991    |
| 11 |    | that we have looked at and you say that you strongly     |
| 12 |    | disagreed with this stance, the stance of not proceeding |
| 13 |    | with targeted look-back. The reason that you strongly    |
| 14 |    | disagreed with that, is that just because of what you    |
| 15 |    | have just told us?                                       |
| 16 | A. | Yes.   |
| 17 | Q. | What discussions did you have with the director of       |
| 18 |    | Southeast BTS, Dr Brian McClelland, about this at that   |
| 19 |    | time?  |
| 20 | A. | I can't remember at what stage it happened but some time |
| 21 |    | between March 1991 and the introduction of testing       |
| 22 |    | in September. I remember saying to Brian, "Right, I'm    |
| 23 |    | going to be doing this and I hope you will support it",  |
| 24 |    | and he said, "Yes, I will support it."                   |
| 25 |    | How that was fed back to Professor Cash, if it was       |

1 formally fed back, I can't remember, and I have no 2 record of me having written back to John Cash about that, nor of Brian doing so. But I'm sure that we had 3 that conversation. 4 Q. Yes. So that would be at some point between March 1991 5 and September 1991? 6 7 Α. Yes. Do you remember any other discussions you had with 8 Q. Yes. 9 other SNBTS members about this topic? 10 Not specifically in detail but one of the groups that Α. Professor Cash had set up was the donor consultants 11 12 group, chaired by George Galea, and I'm sure that, you 13 know, we discussed it there and I told him what I was 14 doing. 15 Yes, okay. Just focusing on before the start Ο. in September 1991, was this an issue that was being 16 17 debated by people in the blood transfusion community? 18 Yes, and it was being debated internationally. As Α. 19 I said, we went to international meetings every year, 20 everybody was talking about it and everybody basically 21 was saying, "No" apart from a few relatively small 22 countries. Holland was one of the ones who did it right 23 from the start. But the United States in particular 24 said they weren't going to be doing it and that 25 influenced a lot of people, obviously.

Q. What was the rationale presented at that time for not
 doing it?

It was largely the numbers, the resources and one of the 3 Α. problems was the United States were still screening with 4 first generation kits at that stage, and the debate over 5 there had been raging since they started testing quite 6 7 early in 1990. So by 1992 they would have had a vast 8 back load of people to follow up if they were going to 9 do it and the longer it went on, the harder it became to 10 take that on board, I think, and they were still using first generation kits up until, I think it was, the 11 12 middle of 1992.

13 So they had a vast number of people, most of whom 14 were false positives. And that was a problem for them 15 which we didn't have because long before we started testing, we knew we would have the second generation 16 17 test, which was much more specific and more sensitive; 18 it would have picked up more of the true Hepatitis Cs as 19 well. Plus, we had the confirmatory test, where we knew from the turn of the years 1990/1991 that we would have 20 21 a second generation test and a confirmatory test, and 22 with Peter Simmonds's work in Edinburgh, Scotland was 23 one of the very few countries, possibly the only 24 country, that had PCR testing as part of our 25 confirmatory algorithm right from the start. When we

1 identified a donor after testing started

| 2 | in | September  | 1991  | and | our  | virol | logist | said,   | "This   | donor |
|---|----|------------|-------|-----|------|-------|--------|---------|---------|-------|
| 3 | is | HCV-posit: | lve," | we  | knew | they  | were   | HCV-pos | sitive. |       |

So the starting point -- that reduced the numbers that we would have to follow up from something like 0.5 to 0.6 per cent to something less than 0.1 per cent, as we discovered when we started testing, and knew indeed from the exploratory work with the second generation tests -- we knew that the numbers would come down by that factor.

11 Q. Just to give us an idea of, you know, the scale of the 12 work, what difference did it make whether you did 13 targeted look-back with a first generation test and 14 targeted look-back with a second generation test and PCR 15 testing?

16 A. It reduced it almost by a factor of 10, almost tenfold. 17 Depending on your local population -- and as I say, with 18 first generation tests we were looking at something like 19 0.5/0.6 per cent. So five or six per thousand, five or 20 six per day. And as I said, in the run-up, in our 21 initial deliberations we were reckoning anything up to 22 ten a day in Scotland.

I'm sure you are going to come on to the paper we
published, but if you look at our first six months'
experience, in Southeast Scotland we had 20 positives in

| 1  |    | the first six months. So vastly less than the first      |
|----|----|--|
| 2  |    | generation tests would have thrown up.                   |
| 3  | Q. | Yes. Could you give us a ballpark figure for, you know,  |
| 4  |    | infected donors on the basis of the first generation     |
| 5  |    | test?  |
| 6  | Α. | Well, infected donors would have been fewer because it   |
| 7  |    | was a less sensitive test but we had no way of           |
| 8  |    | separating out who were the false positives until we had |
| 9  |    | confirmatory testing, and in fact it was the             |
| 10 |    | confirmatory testing, the RIBA and the PCR, that made    |
| 11 |    | the huge difference. We could eliminate all of the       |
| 12 |    | false positives because even with second generation      |
| 13 |    | testing, you do get false positives.                     |
| 14 | Q. | So the point is, if I'm following, Dr Gillon, with the   |
| 15 | ¥. |  |
|    |    | first generation tests you would have a multitude of     |
| 16 |    | false positives that you would still have to go and      |
| 17 |    | follow up and trace what has happened to previous        |
| 18 |    | donations and so on?                                     |
| 19 | Α. | Yes, and we were geared up psychologically to doing      |
| 20 |    | that, although it wouldn't have been a very satisfactory |
| 21 |    | thing to do and in fact, when you look at the results    |
| 22 |    | ten years later, from look-backs in other countries,     |
| 23 |    | particularly the United States, I think that in those    |
| 24 |    | situations where they were following up on the basis of  |
| 25 |    | first generation tests, of the patients they then        |
|    |    |  |

1 identified, only something like between 10 and 2 15 per cent turned out to be HCV-positive, whereas all of ours, all of the patients that we identified through 3 targeted look-back, had been infected and that's because 4 we knew that the donors that we were basing this on were 5 6 carrying the virus. Yes. So much more than half of the work that would have 7 Ο. 8 to be done was unnecessary? 9 Α. Was unnecessary and disturbing no doubt for the 10 patients. Yes, of course. So --11 Q. 12 THE CHAIRMAN: Can I just ask one question here? How far 13 ahead was Professor Simmonds or Dr Simmonds at the time 14 of the rest in having the PCR available? 15 He was -- it's hard to be specific about that because of Α. 16 course people catch up very quickly once you start 17 publishing work, and a lot of what he was doing was 18 based on what we were already doing in developing 19 genetic trees of viruses and looking at animal models and so on. But he was certainly ahead of the game 20 21 internationally, and I think very few countries had PCR 22 as part of their confirmatory algorithm for blood 23 transfusion for a year or two after that. 24 THE CHAIRMAN: A year or two is really quite a long time in 25 the context.

1 A. It's quite a long time and it's worth pointing out that 2 south of the border there was no PCR again for at least 3 a year or two afterwards. THE CHAIRMAN: Sorry, Mr Gardiner, for interrupting your 4 5 thoughts. MR GARDINER: Thank you. 6 7 So if we are talking about March 1991, at that stage 8 you would be anticipating first generation testing. Is 9 that right? No, by then we knew -- by then in fact we had a second 10 Α. generation test and we had the RIBA test. So we had 11 12 confirmatory tests. I can't remember exactly when we 13 knew that we would be able to do PCR on all of the 14 reactive samples, but certainly before September we knew 15 that Peter Simmonds' laboratory was geared up to do 16 that. 17 So if you didn't actually have the PCR testing Ο. by September 1991, you knew that it was on its way 18 19 fairly shortly? A. We knew that it was in development and they were working 20 21 on it and looking at samples, and there were things to 22 iron out, very great problems of contamination and so 23 on. So it needed a dedicated laboratory and it takes 24 a lot of sorting out but they were well on the way by 25 then, and certainly before September we knew it was

1 feasible.

| 2  | Q.  | Yes. So you take this decision in the context of   |
|--|-----|--|
| 3  |     | knowing that you are not going to be using a first   |
| 4  |     | generation test  |
| 5  | Α.  | That's true, yes.  |
| 6  | Q.  | We heard from Dr Alexander yesterday and perhaps I could   |
| 7  |     | just show you a bit of his report just quickly. Could  |
| 8  |     | we have [PEN0181360]? This is the first page of his  |
| 9  |     | report. He says:   |
| 10   |     | "Screening for Hepatitis C virus (HCV) antibody was  |
| 11   |     | introduced in September 1991 through virology  |
| 12   |     | laboratories working within public health (largely).   |
| 13   |     | This was performed with a first generation ELISA."   |
|  |     |  |
| 14   |     | Is that right?   |
| 14<br>15                                     | Α.  | Is that right?<br>I don't think that's correct. I don't think in any part  |
|  | Α.  | -  |
| 15   | Α.  | I don't think that's correct. I don't think in any part  |
| 15<br>16                                     |     | I don't think that's correct. I don't think in any part<br>of the UK a first generation test was used at that  |
| 15<br>16<br>17                               |     | I don't think that's correct. I don't think in any part<br>of the UK a first generation test was used at that<br>stage.  |
| 15<br>16<br>17<br>18                         |     | I don't think that's correct. I don't think in any part<br>of the UK a first generation test was used at that<br>stage.<br>CHAIRMAN: I think that he went on to say that they  |
| 15<br>16<br>17<br>18<br>19                   |     | I don't think that's correct. I don't think in any part<br>of the UK a first generation test was used at that<br>stage.<br>CHAIRMAN: I think that he went on to say that they<br>followed up some 200 people on the basis of these   |
| 15<br>16<br>17<br>18<br>19<br>20             |     | I don't think that's correct. I don't think in any part<br>of the UK a first generation test was used at that<br>stage.<br>CHAIRMAN: I think that he went on to say that they<br>followed up some 200 people on the basis of these<br>initial tests, who were eventually proved not to carry   |
| 15<br>16<br>17<br>18<br>19<br>20<br>21       | THE | I don't think that's correct. I don't think in any part<br>of the UK a first generation test was used at that<br>stage.<br>CHAIRMAN: I think that he went on to say that they<br>followed up some 200 people on the basis of these<br>initial tests, who were eventually proved not to carry<br>infection at all. So   |
| 15<br>16<br>17<br>18<br>19<br>20<br>21<br>22 | THE | I don't think that's correct. I don't think in any part<br>of the UK a first generation test was used at that<br>stage.<br>CHAIRMAN: I think that he went on to say that they<br>followed up some 200 people on the basis of these<br>initial tests, who were eventually proved not to carry<br>infection at all. So<br>They would have done that with second generation and |

a one band positive, and that band could be anything
from 1 plus positive to 4 plus positives and we, with
Peter Simmonds, did a lot of work on this and some of
these were in fact true antibody with a PCR positivity.
And down south they would have been classified as
"indeterminate", and it may well be that that's they are
referring to.

8 THE CHAIRMAN: I think actually it's the next paragraph that 9 he mentioned the 200:

10 "... following up equivocal tests, nearly 200 at one 11 stage."

12 Yes, it suggests to me that those were what we labelled Α. 13 as "indeterminate", and we were able to drill into that 14 a little bit and find some that were PCR-positive. But 15 it was likely to be the case that some of those who were PCR-negative still had true antibody. In other words, 16 17 they had not only cleared the virus but had cleared some 18 of the bands of their antibody as well. But having said 19 that -- and this is moving on five or six years -- once 20 we started doing the look-back, after we had got rid of 21 the backlog of what we knew were true cases, we looked at the indeterminates, and those that were PCR-negative 22 23 had never transmitted to a patient.

24 PROFESSOR JAMES: It is also fair to just note that in the 25 first of the paragraphs on the screen, he said that PCR:

1 "... often in-house was not introduced until around 2 1993 and 1994 in most centres in the UK." So first that does show that you were sort of ahead 3 of the game in that through Peter Simmonds and sort of, 4 in a sense, in perhaps a privileged position from that 5 point of view. 6 7 Second, it suggests where the 200 that the Chairman 8 referred to came from, because there was obviously 9 an 18-month or so period in many parts of the UK where 10 actually they still only had the RIBA confirmatory test, which, even in the second generation wasn't thought to 11 12 be that much of an advance, really? 13 A. Yes, I agree with that, yes. MR GARDINER: It might be helpful, sir, to have a quick look 14 15 at the Preliminary Report about this. Could we go to 16 page 314? At paragraph 9.263. 17 In March 1991 you knew that there were second 18 generation tests but also that they were available. A. Well, I think we were using them in some of our 19 evaluation studies by that stage. I'm not sure exactly 20 21 when that started. Q. If we look at paragraph 9.263, this is from the 22 23 Preliminary Report, it says: 24 "On 8 April 1991 Abbott's product manager announced 25 the launch of Abbott's second generation anti-HCV ELISA

1 test."

| 2  |    | And the footnote at the bottom of the page tells us   |
|----|----|---|
| 3  |    | that this comes from the chronology set out in the  |
| 4  |    | minutes to the ad hoc meeting of the ACTTD.   |
| 5  | Α. | That, of course, means that that's when it became   |
| 6  |    | commercially available, and there was a lot of  |
| 7  |    | development work had gone on by then, and I'm sure we   |
| 8  |    | had done some of that.  |
| 9  | Q. | Yes. So you, in March 1991, had no doubt that it would  |
| 10 |    | be on the basis of the second generation test   |
| 11 | Α. | I think that was the assumption that I would have made.   |
| 12 | Q. | Yes, thank you.   |
| 13 |    | We heard yesterday about a symposium in October 1993  |
| 14 |    | on Hepatitis C virus infection but just very broadly,   |
| 15 |    | between March 1991 and this symposium, do I take it that  |
| 16 |    | the debate about whether to proceed with targeted   |
| 17 |    | look-back was ongoing in the blood transfusion  |
| 18 |    | community?  |
| 19 | Α. | I think it was, but it probably took a back seat to some  |
| 20 |    | extent because, of course, just introducing the testing   |
| 21 |    | was a pretty major preoccupation and getting in place   |
|    |    |   |
| 22 |    | all that was necessary for the confirmatory algorithms,   |
|    |    | all that was necessary for the confirmatory algorithms, for dealing with the false positives, for counselling |
| 22 |    |   |

1 there was a war going on in the Gulf in 1991. So there 2 was lots of stuff. There were huge preparations went on for the Gulf War. So, yes, I think it took a back seat 3 but it didn't go away. 4 We did wonder whether the reference to "national events" 5 Ο. 6 might have been a reference to the war. 7 Α. It's entirely possible. I remember I was on the 8 committee locally that was working -- the SHHD had 9 commandeered a hangar at Turnhouse and we were filling 10 it with blood and preparations for all these wounded soldiers. Mercifully it never happened but there was 11 12 a huge amount of preparation. 13 When it came to September 1991, you simply went ahead Q. 14 with targeted look-back in your region, southeast? 15 That's correct, yes. Α. 16 Just remind us geographically what that encompassed? Q. 17 Α. That encompassed all of the Lothians, the Borders and Fife. 18 Yes. What did that involve, work-wise, for you? 19 Q. For me that meant that -- well, if we look at the 20 Α. 21 information that was in the paper in the first six 22 months, we identified 15 regular donors, which is not 23 a huge number, and based on that, I think, in the paper 24 we described that that gave rise to 60-odd previous 25 donations which turned into 83 previous components

issued. And it's on the basis of each individual
 component issued that you then go through the process of
 identifying where that went, to which hospital, which
 blood bank, which patient, which consultant was in
 charge at the time.

Q. Yes. Ultimately, you wrote a paper about this. Can we
have a look at [LIT0013802]? This is:

8 "Risk of Hepatitis C in patients who received blood
9 from donors subsequently shown to be carriers of
10 Hepatitis C virus."

11 Could you tell us who the different authors are? 12 A. Yes. The first author was Dr Yasmin Ayob, who was 13 seconded to us from the blood centre in Malaysia, where 14 we had had contacts previously. She was a haematologist 15 in training moving into a career in transfusion medicine 16 and came here to basically just observe what we do and 17 I think was with us for about a year.

18 And one of the things that gave her an insight into 19 the nuts and bolts of how our transfusion service worked 20 was to take part in this and I offered her the chance to 21 help with this while she was here. I can't remember if 22 it was right from the start of testing into 1992 or if 23 it was at some point during 1992. But largely what she 24 provided was hands-on experience at looking at medical 25 records, at sorting out that transfusion did take place

1 on such and such a date and this is the consultant that 2 needs to be written to and so on.

Jan Davidson I referred to earlier, who is on our 3 initial group reporting to Professor Cash and who was 4 trained in counselling. Aileen Baxter was my secretary 5 6 and she must be one of the few medical secretaries to 7 get her name on a scientific paper and she did more work 8 than anybody in this. She was fantastic and she did 9 a lot of this chasing up of medical records and taking 10 care of all the correspondence and documentation.

11 Tony Jordan was the lab manager in our local 12 virology testing laboratory. Peng Lee Yap was a fellow 13 consultant who had an interest in this area, who was 14 responsible for the intravenous immunoglobulin service 15 and had some experience of dealing with their problems 16 with non-A non-B Hepatitis.

MR GARDINER: Sir, before we get into the detail -THE CHAIRMAN: I think it's a good time to stop. We have
seen Dr Yap's name often but not managed to see him.
(11.03 am)
(Short break)

22 (11.27 am)

23 THE CHAIRMAN: Mr Gardiner?

24 MR GARDINER: Thank you, sir.

25 Just before we go back into the Ayob paper,

yesterday we noticed that your report, which was referred to at various advisory committees down south, despite the fact that they were often expressing concern about proceeding with targeted look-back, always still included that question on page 9, and we just wanted to ask you: do you remember ever removing that question yourself?

I don't. It's a puzzle to me what happened after that 8 Α. 9 draft 4, I think it was, we saw from February/March. 10 I think I lost ownership of the document. It took on a life of its own, circulating round committees. But at 11 12 the same time, you know, I had been asked to draw up 13 an SOP and we were asked to provide leaflets and so on for donors and I know we did that. I haven't got any of 14 15 those initial leaflets from that time.

16 So we worked on that and no doubt, in leaflets for 17 donors and so on, we dropped that question but that 18 document, I'm sure, just went off into a parallel 19 universe of some sort.

20 THE CHAIRMAN: Because in a real sense the documents weren't 21 as important to you after you had taken the decision 22 that you were going to go ahead in the southeast and 23 do --

24 A. That's right.

25 THE CHAIRMAN: -- the testing anyway. The debate is less

significant once you are committed to a line of action
 that is independent of the outcome.

A. That's true but there were national documents to be used
to give to the donors when we saw them, and the other
four regions, they couldn't have included that question.
So I'm sure it was dropped.

7 MR GARDINER: Yes. Just on that topic, was there any 8 question that you were hiding what you were doing at 9 that time?

10 A. No, absolutely not, no. As I have said, I'm sure that 11 I shared it with the donor consultants' group. They 12 knew what I was doing. If they asked me any questions 13 about it, I would have told them.

14 Q. Yes. Mr McIntosh, when he gave evidence, suggested that 15 a consideration for you and Dr McClelland might have 16 been the Newcastle experience and that you might not 17 have been publicising what you were doing with targeted 18 look-back because you were concerned that the same thing 19 might happen to you. What's your comment?

20 A. I didn't think it was at the forefront of our minds.

I thought that in doing this we might get some trouble, I have to say. I didn't anticipate that it would all go swimmingly.

24 Q. What sort of trouble were you anticipating?

25 A. Well, I thought that Professor Cash probably wouldn't be

1 too pleased and he probably wasn't too pleased, but he 2 never expressed that directly to me in any way. Q. Have you ever discussed starting targeted look-back 3 in September 1999 with Professor Cash? 4 A. Afterwards, do you mean? 5 Yes. Subsequently. 6 Q. 7 Α. After having done it? Q. Yes. 8 9 A. Not that I can remember. 10 So you never told him, if you like, that that's what you Ο. were doing? 11 12 A. I don't remember asking to see him to explain that or 13 him summoning me and/or Brian to do the same but I'm 14 sure we must have talked to him about it, Brian and I, 15 but I have no specific recollection of any discussion. THE CHAIRMAN: Is it too cynical to wonder whether there are 16 17 some topics that are just better not discussed? Entirely possible, yes. 18 Α. 19 THE CHAIRMAN: Yes. 20 MR GARDINER: The paper that we looking at at the moment --21 this is the Ayob paper -- was received on 22 23 November 1993, accepted for publication on 23 21 July 1994. When would you have produced the final 24 draft of this or when would it have been produced, do 25 you think?

1 A. I think that, if it was sent to the journal

| 2  |     | in September, we must have started work on that at the   |
|----|-----|--|
| 3  |     | end of 1992, because it would have gone through a couple |
| 4  |     | of drafts at least and Yasmin Ayob was back in Malaysia. |
| 5  |     | I drafted the paper and I sent it to her at least        |
| 6  |     | once, possibly twice. So to pull it all together, get    |
| 7  |     | it written, get drafts commented on, I guess it was the  |
| 8  |     | end of 1992/maybe the beginning of 1993 at the latest    |
| 9  |     | that we started doing that.                              |
| 10 | Q.  | Yes. Do you think by that stage you had had              |
| 11 |     | a conversation with Professor Cash about the targeted    |
| 12 |     | look-back that you were doing?                           |
| 13 | Α.  | It's highly likely. But I don't remember it being        |
| 14 |     | a specific subject of a meeting.                         |
| 15 | Q.  | Yes.   |
| 16 | A.  | One of the questions that arose is how and when did it   |
| 17 |     | become known as a "pilot study", and I have no clear     |
| 18 |     | recollection of that at all.                             |
| 19 | Q.  | Yes. Do you think it was after it was published or       |
| 20 |     | before it was published that it started to be called     |
| 21 |     | a "pilot study"?   |
| 22 | Α.  | I think it was before. I think probably it was being     |
| 23 |     | referred to, in correspondence and meetings before then, |
| 24 |     | as a "pilot study".                                      |
| 25 | PRC | FESSOR JAMES: Could I ask: did you present the data from |
|    |     |  |

this, say, at the beginning of 1993, when you and Dr Ayob had, you know, kind of done the work? Did you present it at meetings and so on, so actually it was out there, from, you know, 18 months before it actually got into print?

A. Certainly. I think you may all have been circulated
with this paper, which is the proceedings of the
meetings that Professor Cash referred to at the College
of Physicians in October 1993, and in fact in my
presentation, I gave the results then. So we already
had the results at that stage. We were openly sharing
that.

MR GARDINER: So we are going to have a look at that a little later but do you think that you would have presented the data publicly at a time before the symposium?

17 A. I think we probably did a poster to various meetings.
18 I haven't listed posters in my CV. So I had no easy way
19 of checking that but I'm pretty sure we had -- the
20 figures were out there.

21 Q. When you say a "poster", could you explain what that 22 was?

A. For scientific conferences you have the option of
putting in your work either to be presented as an oral
presentation or as a poster, which is where you

1 effectively write the paper and draw up the graphs and 2 so on and put them on a poster, which is in a hall with 3 all the other poster presentations for people to go and look at and read, and you stand beside it and answer 4 questions. And I'm pretty certain we did that but 5 6 I can't remember specifically. 7 Q. Before October 1993? A. Around that time. 8 9 O. Around that time. 10 The national meeting of the British Blood Transfusion Α. Society met in September, as many medical organisations 11 12 did? 13 PROFESSOR JAMES: Dr Ayob was by this time the other side of 14 the world, so it would make sense for you to present it 15 on her behalf as a poster sort of thing at that meeting. 16 I regarded it as my work primarily, rather than hers, Α. 17 I must say, although she was first author. 18 MR GARDINER: Are you able to help us with the question of 19 who it was who first started to talk about this work as a "pilot scheme"? 20 21 Α. I am afraid I can't. I can't remember specifically who 22 came up with the term. 23 Q. Someone at SEBTS or someone external, do you think? 24 Α. It was either Brian McClelland and I together or 25 John Cash with or without input from us. I'm sure he

1 wouldn't have started calling it that unless we knew we 2 were going to do that. So at some point we decided we 3 were going to do that but I can't remember who came up with ... I think we had already used that term, for 4 instance when we did our autologous transfusion work, 5 6 I'm sure we called that a "pilot study". So that had 7 already been established. You weren't unhappy to call it that? 8 Q. 9 Α. No, in fact I do remember in a fit of corporate loyalty 10 referring to it in a meeting as the "SNBTS pilot study" and being sharply reprimanded by Professor Cash, it was 11 12 not to be regarded as the "SNBTS pilot study". 13 Why was that? Q. 14 THE CHAIRMAN: It's making more and more sense. 15 Well, either he didn't want to be associated with it or Α. 16 he felt that it had the potential to damage the 17 reputation of SNBTS, and if that was the case, I was 18 happy to go along with that and regard it as our pilot 19 study. MR GARDINER: When would that have happened, do you think? 20 21 It may well have been after this meeting in the college. Α. 22 It was after a meeting, I think, around that time but 23 I can't remember specifically. 24 Q. So around about the time of the symposium 25 in October 1993?

1 A. Yes, I'm sure it was about that time.

| 2  | Q. | Okay, thank you very much. Could we go to the Ayob      |
|----|----|---|
| 3  |    | paper, and we see in the summary, in the second         |
| 4  |    | paragraph:  |
| 5  |    | "In the first six months of routine testing, 42,697     |
| 6  |    | donors were tested. Of 20 confirmed to be HCV-positive, |
| 7  |    | 15 were regular donors. 83 components were prepared     |
| 8  |    | from 63 anti-HCV-positive previous donations from these |
| 9  |    | donors. In all, nine recipients were found to be alive. |
| 10 |    | All were positive for anti-HCV."                        |
| 11 |    | Was that a surprising finding, the amount of            |
| 12 |    | confirmed HCV-positive donors?                          |
| 13 | A. | Yes, I think it was a bit surprising that we found so   |
| 14 |    | few who were alive at that stage, having done it as     |
| 15 |    | rapidly as we could really.                             |
| 16 | Q. | Yes. Did it accord with your predictions before you     |
| 17 |    | started to do the look-back?                            |
| 18 | A. | I don't think we did have a feel for how much we would  |
| 19 |    | turn up really. I don't think we predicted that.        |
| 20 |    | I know that we went on from these data to predict       |
| 21 |    | roughly the numbers we would find in Scotland, which    |
| 22 |    | turned out to be eerily correct, but at that stage we   |
| 23 |    | didn't know what we were going to find.                 |
| 24 | Q. | If we look at the methods on the second column, that    |
| 25 |    | talks about the different tests. Could you just talk us |

1

## through the methods that you used?

A. This was exactly the testing that was in place throughout Scotland at the time, which was that every donation that was collected was subjected, along with the other routine tests, to what's known as an ELISA that is a rapid screening test with fully automated test.

That would tell us which donations were reactive in 8 that test system. Those were then selected and of 9 10 course, as soon as they were regarded as reactive in the screening test, the actual donations, the bags of blood 11 12 and platelets and so on, were taken out of circulation 13 and put into quarantine, while a sample which was taken 14 from the pack was sent across to the Microbiology 15 Reference Unit for further extended testing, which usually included, where we could, if we had an ELISA 16 17 from a different manufacturer, plus what was known as 18 the supplementary test, the RIBA-2 -- is what we were 19 using, which just tells you about antibody and breaks it 20 down into various different sub-portions of an antibody, 21 and these appear as bands on a strip.

It's a very visual thing and two bands or more was regarded as positive, a single band, as I described earlier, was described as an "indeterminate test", and of course it was negative if nothing showed up. And

there were control bands as well, which tell you that the test was done properly, and in addition we had the PCR, which looked directly for the genetic material of the virus.

## 5 Q. What did you do with the indeterminates?

We regarded them as potentially positive and would not 6 Α. 7 have cleared a person with an indeterminate result to go 8 back on to the panel of donors who were able to donate. 9 Eventually that policy was revised, once we knew --10 the data I gave you earlier -- that in fact, if the PCR was negative, these donors did not transmit. And some 11 12 years later we raised this subject and -- I think it was 13 agreed at UK level, in fact, rather than just Scottish 14 level, that those donors could be reinstated in fact. 15 But we were very cautious initially about that. 16 Yes. The next paragraph talks about donor call-up and Q. 17 counselling. Could you just briefly describe how that

18 was done?

19 A. We had agreed that we would send out a letter with 20 standardised wording to the donor, which was really 21 pretty bland, and this was not an easy thing to decide 22 on in fact because if it was too bland, there was 23 a danger the donors wouldn't take it seriously and come 24 back to see us, which would not be good for the donor. 25 In a sense it wouldn't matter to us because obviously we

would never recall them to donate and if they did come
 back in, we would not allow them to donate. But we
 wanted them to come back.

4 So it had to give enough information to make them 5 think, "We had better go and see these people and see 6 what this is about". And we also wanted to get a second 7 sample to confirm the findings and make sure that that 8 person got proper medical care thereafter.

9 Q. Yes. If we go over the page to the second paragraph on 10 the left-hand column, the heading is "Recipient 11 identification"; could you just explain to us what you 12 did with that?

13 The first sentence ties in with what Professor Cash was Α. 14 saying yesterday. What we say is we identified from 15 blood bank records -- and he was right in saying that in the Southeast of Scotland we had very direct access to 16 17 the majority of the relevant records because we were 18 sited in the Royal Infirmary of Edinburgh. We had the 19 blood bank under our control, and I could in fact just 20 ask for medical records in the Royal Infirmary, for any patient's records, and get them usually within 24 hours 21 22 or so.

In fact where he was wrong yesterday was in suggesting that made it easier for us. It gave us more work because we were doing the part that in an outside

hospital -- say, if we identified a donation that had gone to the Western General hospital, I would have written to the consultant there saying, "We sent you this unit on [such and such a date]. We now know that donor is HCV-positive and we have to regard this one as potentially positive; can you tell us what happened to it?"

8 And he would have to do that bit of work identifying 9 what happened to what unit of blood, who the patient 10 was, who the consultant was in charge of the patient and 11 then report back. So in fact it gave us more work but 12 of course it was faster, because we could do it 13 ourselves without correspondence and so on.

14 So for a large slice of them we could get that 15 information relatively quickly. Otherwise I had to 16 write to whoever it was at the Western General or in 17 hospitals in Fife and the Borders or West Lothian or 18 wherever, and ask them to do the same.

Q. So that was more work for you but it allowed the
operation to be concluded quicker because you had more
control over the medical records. Is that right?
A. Yes, it undoubtedly speeded it up a bit because there
were certain steps that were vital to know about: had
the unit been transfused? Who was the patient? Is the
patient still alive? And you could often tell that from

1 the hospital records.

2 Dr Gillon, I wonder if you could move your microphone Ο. a little bit closer, I'm not sure that it's picking you 3 4 up. If we go on the left-hand column, we see "Results" 5 and again we see: 6 7 "Between 1 September 1991 and 29 February 1992, 8 42,697 donors were screened routinely." 9 It then lists all the results. Could you just 10 broadly tell us what the results were that you got back from this exercise? 11 12 A. Well, what we saw was that, I think these 15 donors had 13 given 60-odd donations that we knew about -- sorry, 70 14 previous donations, and that led to 80-odd components, 15 which we had to establish the fate of in the way that I have just described to you. 16 17 0. Yes. A. So although the number of donors looks modest, of 18 19 course, because they have been donating for many years, 20 the number of components you have to chase up was not 21 inconsiderable, manageable but not inconsiderable. 22 Q. Yes. If we could go to the top of the right-hand 23 column, there is a figure 1, "Plan of Investigation". 24 Could you just explain to us what that is? 25 A. This is just trying to make it easily accessible, this

1 system that we had in place, which was screening, 2 leading to the reactive donors being identified and the 3 confirmation of those who were genuinely infected with Hepatitis C, what we did about the donor. And then, 4 beyond that, is the look-back process itself, when we 5 review the record, if there are frozen samples, retrieve 6 7 them and test them. If we could identify the date of 8 seroconversion, that could cut things down considerably, 9 because if we could show that, say, a donor had been 10 regularly donating from, let's say, 1984 to 1991, and in Edinburgh, we might well have had samples for all of 11 12 that time, we would pick out initially the first and the 13 most recent test there. If they were both positive, we 14 would assume everything in between was capable of 15 transmitting infection. If the earlier one was negative, we would then dig out the intervening 16 17 samples -- depending on how many, we might do them one 18 at a time, we might do them all at once for convenience. 19 If we could then establish that at a certain point,

20 the donor had gone from seronegative to seropositive, 21 particularly valuable if that coincided with what the 22 donor was telling us about risky activity, we would 23 usually in fact go back and trace the recipients of the 24 previous negative donation, in case it was what was 25 called a "window period donation". But anything prior

| 1  |    | to that we can discount and not trouble the patients    |
|----|----|---|
| 2  |    | with that information.                                  |
| 3  | Q. | What does the dotted line represent?                    |
| 4  | A. | Just the start of the look-back process.                |
| 5  | Q. | Right. So that's the look-back?                         |
| 6  | A. | Yes.  |
| 7  | Q. | The targeted look-back portion? Thank you.              |
| 8  |    | If we could go down to the bottom of the second         |
| 9  |    | column, you say in the conclusion:                      |
| 10 |    | "The workload was assessed as approximately 60 hours    |
| 11 |    | each of secretarial time and medical time."             |
| 12 |    | 60 hours each?  |
| 13 | A. | Yes, I mean, that was a best guess at what Yasmin Ayob  |
| 14 |    | and my secretary had put in to that first six months'   |
| 15 |    | work. It would have spanned a longer period than the    |
| 16 |    | six months because, you know, these donors would have   |
| 17 |    | been coming back through that period and some of them   |
| 18 |    | towards the end of it. We would not have been getting   |
| 19 |    | the look-back completed for at least six months after   |
| 20 |    | that probably, which was around the time we started     |
| 21 |    | writing this up, I think.                               |
| 22 | Q. | So 60 hours of secretarial time and 60 hours of medical |
| 23 |    | time?   |
| 24 | Α. | Yes.  |
| 25 | Q. | Okay. Then microbiology staff, small amount of          |

1 consultant time. Was that an important conclusion in 2 terms of the feasibility of targeted look-back? A. As far as blood centre work was concerned, it was better 3 than nothing, I guess. I can't pretend that we did 4 a work study on this and measured all the time that went 5 6 into it but it was guesswork, but guesswork based on 7 experience, just to try and give people an idea with that number of donors, this is how much effort would 8 9 need to go into it. Yes. But what you were telling us previously was that 10 Ο. your particular circumstances in the southeast didn't 11 12 make the process easier or, rather, didn't mean that you 13 were spending less time than if it had been elsewhere in 14 Scotland? 15 It's true that with the exception of Dundee and Α. Aberdeen, and Inverness in fact, this would not have 16 17 been applicable to the West of Scotland in the sense that I reckoned we had more work to do for each 18 19 individual than they would. PROFESSOR JAMES: But somebody else would have had to do the 20 21 work, wouldn't they? 22 And that's where the hospital blood bank would have Α. 23 felt --24 PROFESSOR JAMES: Precisely, just a transfer of the work 25 from you to other colleagues in other hospitals?

1 A. That's right.

| 2  | MR | GARDINER: In terms of the question of whether targeted   |
|----|----|--|
| 3  |    | look-back should be pursued nationally, how did this     |
| 4  |    | paper assist determination of that question in your      |
| 5  |    | opinion?   |
| 6  | Α. | I think at least gave it a nudge. You know, when we      |
| 7  |    | presented it at the meeting in the college I can't       |
| 8  |    | remember but there probably was a poster there would     |
| 9  |    | no doubt have been talk about it and it must have been   |
| 10 |    | one of the factors that revived discussion at the        |
| 11 |    | various committees.                                      |
| 12 | Q. | Yes. I'm just wondering if it was more than that. Is     |
| 13 |    | it putting it too high to say that before your report    |
| 14 |    | people were unsure whether look-back was feasible        |
| 15 |    | without massive resources being put into it and after    |
| 16 |    | your report it was clear that that wouldn't necessarily  |
| 17 |    | be what was required?                                    |
| 18 | A. | I don't know. I would hesitate to read too much into it  |
| 19 |    | because, I mean, I think people saw me as I certainly    |
| 20 |    | wasn't an enthusiast for look-back but somebody who felt |
| 21 |    | strongly that we should be doing look-back. So they      |
| 22 |    | might have looked at these data and thought it's all as  |
| 23 |    | John Cash presented, others might have thought, "Well,   |
| 24 |    | it's all right for them, it's easy for them but we can't |
| 25 |    | do that, we don't want to do that," or, "We don't        |

believe that's the right thing to do". I don't know that the paper would have had that much influence but it must have had some.

But it wasn't the only factor. There were media stories beginning to appear around about that time and I think -- was it the Sunday Mail or one of the Scottish papers, made it a bit of a crusade in the early part of 1994, I think it was.

9 Q. Thank you. If we maybe just look at the next page of
10 this report, there is a diagram that sets out really the
11 results of the exercise.

12 A. Yes, and broadly speaking -- well, almost exactly, this 13 became the format adopted by the monitoring that was in 14 place after look-back was introduced universally in 15 1995, and this is the format in which we reported data 16 in the MSBT eventually.

17 Q. Yes, thank you. Could we go to table 1. These are the 18 results of the different tests that you did. Is that 19 right?

A. Yes, it shows the RIBA pattern. So each of these
columns, the C100, C33C and so on, these bands are
described in the RIBA, whether the PCR was positive or
negative. And the duration is, as I see from the
asterisk, the time from the last reported risk
behaviour, so how long we thought the donor had had that

1 infection. And then comparing that with the results we 2 found in the recipients. 3 Q. Yes. If we could go over the page, we see there that under the heading of "Discussion", you discuss papers 4 about look-back. At the bottom of the page you note --5 this is five lines up: 6 7 "It is the policy of the UK transfusion services not 8 to carry out HCV look-backs. If we assume approximately 9 one infected recipient per donor, we estimate that 10 around 3,000 patients may be alive and infected with HCV as a result of transfusion in the UK, based on the 11 12 prevalence of HCV in Scottish blood donors and excluding 13 haemophiliacs." 14 Could you just explain that, please? 15 I'm sorry, explain why we excluded haemophiliacs or ...? Α. Well, just if you could explain the numbers --16 Q. 17 Α. The extrapolation is based simply on what we then knew 18 about the prevalence of Hepatitis C in the donor 19 population, as compared with our first six months. And if we extrapolated what we found then to the whole donor 20 21 population, we came up with a number of roughly 300 --22 Yes. Q. 23 -- for Scotland, 3,000 for the UK. It wasn't too far Α. 24 off the mark, given that ultimately the UK total 25 look-back produced over 2,000 in England and 133,

1 I think it was, in Scotland; who were still alive at 2 that time. And of course many of those patients might have died in the intervening --3 Q. Yes, thank you. In the second column at the top you 4 refer to treatment in the form of A interferon. You say 5 6 that: 7 "This compels us to suggest that we have a clear 8 ethical responsibility to these patients to identify 9 them and offer counselling, testing and, if necessary, treatment." 10 There is a reference there to Kolins 1990. What was 11 12 that paper? 13 A. I can't remember the details of that particular paper. I see it was a review article in Transfusion, which was 14 15 the leading blood transfusion journal published in the United States. So this looks as if it was a leader in 16 17 Transfusion which made the same point. 18 Q. Yes. So you are agreeing with what has been said 19 previously about the --A. As I say -- sorry, I think in retrospect that was 20 21 a letter published in Transfusion. I don't know the 22 author; Kolins was not known to me. 23 Q. Yes. In any event, you conclude by saying that in your 24 view: 25 "This problem should not be ignored on logistical

1 grounds when in each case there is an overwhelming 2 responsibility to the individual patients." Is that what your group felt at that time? 3 Yes, certainly our group in southeast were committed to 4 Α. this, yes, and we saw it as a responsibility to the 5 6 patients. 7 Yes, thank you. Could we just go back to 3802? It's Ο. 8 the results page, the second column, the sentence that 9 starts: "Samples were received ..." 10 I just noted there at the bottom of that paragraph: 11 12 "No recipient was alive and traceable more than five 13 years after transfusion." I just wonder if you thought, Dr Gillon, that that 14 15 was an important finding in terms of carrying out targeted look-back? 16 17 Α. Yes, I think that's very much the case. I mean, I think 18 there was already information from the HIV look-backs 19 that something of the order of 50 per cent of patients 20 will have died within the first year or two of having 21 a transfusion and that is, of course, because of the 22 severity of the disease for which they were transfused. 23 And this confirms that, you know, if you go back more 24 than five years, you are not going to find many patients 25 who are still alive. You do find some and we found one

1 or two in our HIV look-back, as we reported in the 2 statistics paper, and indeed in the comprehensive look-back there were some patients identified from, say, 3 the early 80s, but not many. 4 Yes. Would you say that that supports the argument that 5 Ο. look-back should be started as soon as possible? 6 7 Α. Yes, I mean, I think broadly speaking, yes. If you are 8 going to have a chance of doing anything about it 9 anyway, you need to identify the patients sooner rather 10 than later. Thank you. I would like to have a look now at the 11 Q. 12 symposium that we have heard about. The flyer for that 13 is at [PEN0180553]. So that's the first page. We see that it was October 1993. If you could go to 14 15 the next page, please, we see that at 10.30 you are scheduled to deliver a paper on the epidemiology of HCV. 16 17 I think you have kindly produced a copy of that paper today and we have got that in court book now at 18 19 [PEN0181420]. 20 I think this is the introduction to the workshop and 21 your paper is on the next page, 1421. We have got it on 22 the screen now. Is that the paper that you delivered at

24 A. Yes.

the symposium?

23

25 Q. Could you just summarise what you told the symposium

1 that day?

A. What I tried to do was give a fairly comprehensive
overview of what was known about the epidemiology of
Hepatitis C at that stage from a non-epidemiologist's
point of view. And that probably skewed the
presentation a little bit in favour of what we knew
about blood donors and that particular section of the
community.

9 But I tried to cover, for instance, the geography --10 HCV is a worldwide problem and so on. And later on in 11 the paper I covered what was known about sexual 12 transmission and other facts.

PROFESSOR JAMES: Just to note that as a matter of fact this was updated to 1995, so say the editors. So what's written here is perhaps very largely what you presented in 1993 but it will have been modified by information you had, and it's in your references, for example, up to 1995. Would that be correct?

19 A. I think that's correct, yes. I think this was produced 20 from tape recordings of the presentations. It was 21 organised by Dr Gordon Scott, who is a consultant in 22 GUM, and I have a letter from him saying that, you know, 23 "It's taking me a while to deal with these transcripts 24 and, you know, given that it's a couple of year, do you 25 want to look at your numbers and see if anything has

1 changed?"

2 PROFESSOR JAMES: Thank you.

3 A. That's more or less what happened.

MR GARDINER: So we see on that first page that you talked first of all about historical perspective and then geography: HCV is a worldwide problem. If we go over the page, we see on page 585 that you talk about the situation in the United Kingdom, and if we look about two thirds of the way down that paragraph, that sentence starting:

"Nonetheless, some information has been obtained. 11 12 In the two years since testing began in our service, we 13 have identified approximately 300 seropositive donors. 14 We have also tried to extrapolate from this rate of 15 donor, seropositivity, the number of transfusion 16 recipients who have been infected in the past by these 17 donors. In a small study in southeast Scotland, looking at the first 20 HCV seropositive donors to be 18 19 identified, we found that over 70 potentially infectious 20 units of blood had been donated by these individuals. 21 However, many of the recipients of these units of blood 22 died of their primary disease. Some are untraceable and 23 there remained fewer than ten live patients."

Is that you presenting the data that we have seen in the Ayob paper?

1 A. Yes, exactly.

| 2  | Q. | Okay. Then you make an estimate of the 150 infected      |
|----|----|--|
| 3  |    | recipients in footnote 9 on page 588 in the Ayob report; |
| 4  |    | that's right?  |
| 5  | Α. | Yes, and that would have gone in subsequently, yes.      |
| 6  | Q. | Subsequently?  |
| 7  | Α. | It hadn't been published at that stage.                  |
| 8  | Q. | Of course, yes. So do you think that this was the first  |
| 9  |    | time that you were publicly presenting the data that     |
| 10 |    | ended up in the Ayob report?                             |
| 11 | Α. | Yes, I think it probably was, unless we had a poster at  |
| 12 |    | the BBTS meeting in September, which was possible, but   |
| 13 |    | certainly it was around that time.                       |
| 14 | Q. | Are you able to remember how much time was spent on this |
| 15 |    | data?  |
| 16 | A. | In that conference?                                      |
| 17 | Q. | In your particular talk. How much of your talk was       |
| 18 |    | concerned with your experience in the southeast?         |
| 19 | A. | A relatively small part of it. Mainly I was concerned    |
| 20 |    | with the broader epidemiological issues, and in fact at  |
| 21 |    | the end of the proceedings there is a transcript of the  |
| 22 |    | discussion and nobody asked a question about look-back.  |
| 23 | Q. | Yes. Okay. Could we go back to the flyer at page 2 of    |
|    |    |  |
| 24 |    | [PEN0180553]? At the bottom half of the page, the        |

1 Dr Dusheiko and so at the end of your talk there was no 2 question or discussion about targeted look-back. That's 3 right? There was no discussion at the end of the talks; it was 4 Α. all held over to the final session at 3.30. 5 6 O. I see. 7 Α. And Gordon Scott tried to focus on what he thought were 8 the big questions really and as I say, it just didn't 9 come up in that part of the proceedings. 10 Really? We got the impression from Professor Cash's Ο. evidence that Dr Dusheiko would have mentioned the 11 12 question of targeted look-back. Is that your 13 recollection? 14 A. It was but I fished this out last night and I was 15 surprised to find that in his talk he doesn't refer --16 not in his talk, he wouldn't have referred to it but 17 that it didn't come up in discussion. But I have to 18 say, I have the same recollection as John Cash, that 19 Geoff Dusheiko was interested in this and asking us, 20 "Why isn't this happening?" He was coming from a very 21 clinical standpoint and was very interested in the topic 22 obviously. So your recollection is that by the end of the symposium 23 Q. 24 the question of targeted look-back had been publicly 25 discussed?

A. It had been aired and it certainly stimulated -- I'm
 sure it interested Geoff Dusheiko and maybe one or two
 others there.

Q. Okay. Thank you. Could we go back to your statement,
page 2 of [PEN0180410]? In the middle of the second
paragraph you refer to the Ayob paper and you say:

7 "Our conclusion stated in the paper was that 8 look-back was feasible with little in the way of extra 9 resource and justified in terms of outcome and as 10 described in the Preliminary Report, this chapter was instrumental in the decision reached by the committee 11 12 for the Microbiological Safety of Blood and Tissue 13 (MSBT) at its meeting on 15 December 1994 to recommend to ministers that look-back should be undertaken 14 15 UK-wide."

16 I think, if we could have a quick look at the 17 Preliminary Report at page 322. It's paragraph 9.299. 18 What it says is:

"On 15 December 1994 the ACMSBT met. The Committee decided to recommend to ministers that a UK-wide look-back exercise be introduced to identify those blood transfusion recipients infected with Hepatitis C prior to the introduction of Hepatitis C screening in September 1991."

25 If we could go back to Dr Gillon's statement. You

1 then narrate what happens subsequently:

2 "The recommendation was accepted on 11 January 1995.
3 On 3 April 1995 the CMO, Dr Kenneth Calman, wrote to all
4 doctors announcing look-back and an identical letter was
5 issued by the CMO in Scotland to all doctors working in
6 Scotland."

If we could go over the page, you refer to, at the top, a working party set up under the chairmanship of the Deputy CMO and then in the next paragraph you talk about implementation in 1995 and that formal monitoring of the look-back ceased in 1998. At this point I would like to look at the report that you prepared for the Inquiry at -- which is at [PEN0172220].

14 Dr Gillon, could you tell us what this document is, 15 please?

16 A. This is a paper which I prepared, with input from one or 17 two others, in the run-up to the Inquiry starting, when 18 we had a team established in SNBTS to try to get 19 together our materials in preparation for the Inquiry 20 itself. And one of the things we did was identify one 21 or two areas that would merit, effectively, a review 22 paper, which is what this was.

Q. Yes. If we go over the page, we see that this is in
response to a question from Mr Tullis, the Inquiry
solicitor, on 21 April 2010, about what the SNBTS policy

1 was in relation to HCV look-back.

| 2  |    | Could we go to page 2224? These are the contents of      |
|----|----|--|
| 3  |    | the paper. Is that right?                                |
| 4  | A. | Yes, that's right.                                       |
| 5  | Q. | Paragraphs 1 to 2.2 are primarily concerned with HIV.    |
| 6  |    | Would that be fair?                                      |
| 7  | A. | Well, initially just describing the different types of   |
| 8  |    | look-back, as we have discussed today, and some of the   |
| 9  |    | experience, particularly in the United States, with HIV  |
| 10 |    | look-back and then saying what we found when we did HIV  |
| 11 |    | look-back in this country.                               |
| 12 | Q. | Yes. So if we could just go to the section on HCV        |
| 13 |    | look-back, which is at 2231, this is a paper that you    |
| 14 |    | drafted primarily, Dr Gillon. Is that right?             |
| 15 | A. | Yes, Dr McClelland and Professor Franklin had some input |
| 16 |    | to it.   |
| 17 | Q. | Yes. In the first paragraph there you talk about         |
| 18 |    | retrospective analysis in the USA and you talk about the |
| 19 |    | labour-intensiveness of the process, and I think the     |
| 20 |    | footnote at the end of that paragraph is a reference to  |
| 21 |    | a paper by Busch MP. Was that paper important in the     |
| 22 |    | approach to look-back?                                   |
| 23 | Α. | I think it was. Mike Busch worked in San Francisco with  |
| 24 |    | Perkins, who had written his report on the outcome of    |
| 25 |    | the HIV look-back and was the head of the department     |

1 there, and, as I described earlier, they put a huge 2 amount of work into it and got not that much back out of it at the end, in terms of identifying patients. To 3 tell you the truth, I can't remember exactly how 4 enthusiastic or unenthusiastic Mike Busch was in that 5 6 review paper that he wrote -- I think around the end of 7 the 80s, was it, the 90s? We can have a look at it, [PEN0172307]. Perhaps if we 8 Q. 9 could just go to the last page of that, please. This is 10 the end of his article. If we could go to the second column at the top, the paragraph that begins: 11 12 "In light of the data showing the very limited 13 efficacy of previous look-back efforts ... " 14 Just reading that again there, Dr Gillon, do you 15 recall what he was advocating? 16 He seems to be advocating a public education campaign Α. 17 for physicians and the lay public. Good luck to him, that's what I would say. I can't make out if he is 18 19 saying that this would be more effective or just a way 20 of doing something. In fact experience should have 21 shown them in San Francisco that general appeals to the 22 public to come forward for testing do not work. That is 23 something that we considered in the working party set up 24 by the MSBT. To some extent we did that in the press 25 conferences and press releases, when the CMO's letter

came out. And indeed included in the letter to doctors
 was the statement that any patient with a history of
 transfusion who expressed any concern about HCV should
 receive a test.
 Q. Yes.
 A. And in the press releases and so on, patients were
 encouraged to come forward if they were worried, but

8 very few did.

9 Okav. Thank you. If we could go back to the report, Ο. 10 the exposition. In the next paragraph you talk about extrapolation that was done and we have discussed that. 11 12 If we could go over the page, you talk about HCV 13 look-back in Scotland and the pilot study, and we have also discussed that. If we could go over the page, the 14 15 second paragraph, you say:

16 "The outcome of all of this ..."

17 In reference to the work that you did:

18 "... all of the living recipients tested in the 19 initial period were able to be confirmed to be 20 HCV-positive in marked contrast to reports based on 21 first generation tests. The number of donors identified 22 as truly infected with the virus was approximately 23 tenfold less ..."

And you have told us about that already. In the next paragraph you talk about early papers, which are

1 listed in table 1. I wonder if we could have a look at 2 table 1, please, which is at 2236. Could you just explain to us what this table shows? 3 A. At around that time we weren't the only ones that 4 started publishing reports of our own local look-back 5 6 and what I tried to do was compare the various reports 7 that were appearing around that time in terms of the way 8 they had gone about look-back, which tests they were 9 using at the time, what the outcome was in terms of the number of components and recipients traced and 10

11 recipients not traced and deceased and so on, and some 12 studies are better than others.

13 I mean, I think that comes across very clearly just 14 looking at some of the gaps in the Swedish study, for 15 instance, which is even smaller than ours and very 16 little detail given in the paper. But some are very 17 helpful. The Netherlands study was bigger than ours, 18 broadly similar results, and in fact everything that has 19 been published subsequently really reflects the same 20 outcome in terms of the proportion of patients who are 21 deceased by that time, the proportion who are not 22 traceable, and that at the end of it you end up with not 23 that many alive, testable and Hepatitis C-positive 24 recipients.

So I think it broadly confirmed our experience and,

25

| 1  |    | as I say, these were appearing around the same time and  |
|----|----|--|
| 2  |    | must have been influential at that time too.             |
| 3  | Q. | Yes. Thank you. Could we now have a look at the          |
| 4  |    | question of cost-effectiveness of the targeted           |
| 5  |    | look-backs, if we could go back to page 15, please, two  |
| 6  |    | pages back. At the bottom of the page, you first of all  |
| 7  |    | talk about the situation in the San Francisco area.      |
| 8  |    | Could you tell us a little bit about that?               |
| 9  | Α. | Well, I have alluded already to the amount of work they  |
| 10 |    | put into it and I don't know that they ever costed that. |
| 11 |    | I can't remember. But they estimated that of the total   |
| 12 |    | number of patients who had been infected by transfusion  |
| 13 |    | in their area, they only managed to trace about          |
| 14 |    | 3 per cent of them, so they were saying that this is not |
| 15 |    | a particularly effective way of identifying people who   |
| 16 |    | have been infected by transfusion, which nobody would    |
| 17 |    | dispute.   |
| 18 |    | They put an exceptional amount of effort into it, we     |
| 19 |    | put a fair amount of effort into it and others have      |
| 20 |    | tried to cost that. I think there was a Canadian study   |
| 21 |    | which estimated the blood transfusion service bit of it  |
| 22 |    | at something like \$6,000 per patient identified, which  |
| 23 |    | seems cheap.   |

24 Q. I think if we go over the page, we see that.

25 A. But there is a lot more to cost-effectiveness than just

totting up how much time and effort and therefore money
 it took us to identify the patients we identified.
 Q. Yes.

If you are going to do proper cost-effectiveness, you 4 Α. need to look at the outcome beyond that and the impact. 5 6 First of all, we didn't look at the hospital blood 7 banks; it was tracing, tests and so on. The GPs would 8 have had to put some effort into it. Then the patients 9 were referred to specialists. That all cost money. And 10 if they had gone to interferon treatment or a liver transplant and so on, that's even more expensive. And 11 12 you have to say whether that's cost-effective in terms 13 of the outcome, in terms of mortality, morbidity and 14 prolongation of life and so on. So it's complicated. 15 There aren't any really comprehensive studies that 16 address that satisfactorily.

17 Q. Yes. What studies are there on the question of 18 mortality and morbidity, as far as targeted look-back is 19 concerned?

A. The best data have appeared quite recently, both from the outcome of the UK look-back, which gave rise to what was known as the "National HCV Register", which was set up by the NBS, in conjunction with the Health Protection Agency down south, to which we contributed. And what they decided to do and was a tremendous idea was, as we

were doing this look-back, to try to register as many of those patients as possible in a way that could allow prospective follow-up on the basis that we knew the date of infection because, of course, we knew the date when they had been transfused. And this is a uniquely valuable cohort. It is starting to give long-term outcomes in very precise terms.

8 At, I think, about ten years they reported some 9 preliminary findings that round about 20 years, on 10 average, since the time of transfusion, the mortality 11 was no different between patients who had been infected 12 by transfusion and patients who had had a transfusion 13 but had not been infected by Hepatitis C.

14 Q. Yes.

25

A. So they couldn't demonstrate any benefit in terms of length of life. And they have continued this work up until now and I don't think there has been a subsequent report from that group yet but that would give us tremendous data. Meanwhile, a year or two ago the Danish published similar experience.

Q. I think you talk about that in your statement. So perhaps we should just look at that section. It's page 4 of [PEN0180410]. This is in the context of the question:

"How useful do you think the look-back exercise

1 was?"

2 I think you are addressing the best measure of benefit is mortality, and half way through that 3 paragraph you refer to the Danish report. I'm sorry 4 I interrupted you. Could you just carry on? 5 As I say, this is fairly recent and unlike the study 6 Α. 7 I have described, which is in progress in this country, 8 this is retrospective. So two or three years ago the 9 Danish researchers looked back at the outcome of their look-back, which was done around the same time as ours 10 actually, and found out what the outcome for those 11 12 patients was. And again, they could really demonstrate 13 no significant benefit in terms of mortality compared to non-infected transfused patients but they have shown 14 15 very considerable morbidity in the HCV infected 16 patients, which is really quite significant, I think. 17 I see at the bottom of the page there that not many patients were in fact treated with interferon but of 18 19 those who were treated, they got nearly 50 per cent cure 20 rates. So there was beginning to emerge evidence of 21 benefit from that group of patients anyway. 22 THE CHAIRMAN: I wonder if I could follow the mortality

23 point just a little. There is a shift towards

24 liver-related cause of death --

25 A. There is.

1 THE CHAIRMAN: -- reported.

| 2  | A.  | But not enough to affect or cause mortality.             |
|----|-----|--|
| 3  | THE | CHAIRMAN: My concern is that while there perhaps is no   |
| 4  |     | change in the balance between those infected and those   |
| 5  |     | not, if there is a growth in the numbers dying from      |
| 6  |     | liver disease, does that not have some significance?     |
| 7  | A.  | Indeed, but you would hope that can be affected by the   |
| 8  |     | fact that they have been identified and, as we see at    |
| 9  |     | the bottom of the page, offered treatment that might     |
| 10 |     | cure them.   |
| 11 | THE | CHAIRMAN: I see that as a second stage in the argument,  |
| 12 |     | as it were.  |
| 13 | A.  | Yes.   |
| 14 | THE | CHAIRMAN: But the mortality risk has been increased by   |
| 15 |     | infection and that can be offset by treatment but of     |
| 16 |     | course the risk is there first, is it not?               |
| 17 | A.  | Yes, indeed. It's a question of whether you would want   |
| 18 |     | to identify that in advance and potentially be able to   |
| 19 |     | do something about it.                                   |
| 20 | THE | CHAIRMAN: Sorry, Mr Gardiner.                            |
| 21 | MR  | GARDINER: I think that Danish study is at [PEN0180507].  |
| 22 |     | Is that it?  |
| 23 | A.  | Yes, that's it.  |
| 24 | Q.  | So this contains information about mortality but does it |
| 25 |     | contain information about morbidity as well?             |
|    |     |  |

1 Yes, it does, I'm sure this is the paper that has Α. 2 morbidity included. Q. When we talk about morbidity, we are talking about 3 living with the disease? 4 Living with the disease, having cirrhosis and the 5 Α. 6 implications of cirrhosis, which are very severe and in 7 themselves life-threatening. 8 Q. Yes. So that's a treatment for people who are living

9 with the disease and benefit from that is an indication
10 in favour of targeted look-back, I think. That's what
11 you are saying.

12 A. Yes, I think that's true, yes.

Q. Okay. We can put that away now. Could we go back to Dr Gillon's statement, please? Again, this is still in the context of the question of how useful targeted look-back was and in the third paragraph you talk about your own personal experience of counselling. Could you tell us a bit about that, please?

19 A. From the outset, when we did the look-back -- and this 20 became standard practice in the UK general look-back --21 I offered the clinician responsible for the patient 22 first chance to talk to the patient and counsel them if 23 they wanted. If they didn't want to do that, we went 24 through the GP and the GP in some cases took that on 25 board. For instance if they were out in Fife or down in

1 the Borders, they might well do that. But most of the 2 patients in fact ended up being seen by me and I saw most of them in the clinic I was still doing in the GI 3 unit at the Western General Hospital, rather than in the 4 donor centre. I think I may have seen one or two in the 5 donor centre but I did the initial counselling of quite 6 7 a few of these patients and followed them up for a short 8 time afterwards. And I never had any negative feedback 9 from patients that we shouldn't have done this, they 10 would prefer not to have known. That didn't happen. Small numbers obviously. 11 12 And you say in the next paragraph: Q. 13 "However, since clearly measurable benefit has not 14 (yet) been demonstrated, a cost-effectiveness analysis 15 cannot be undertaken." 16 So are you suggesting that maybe in the future, when 17 we have more data, that exercise will be able to be carried out? 18 I would hope. So I would hope that's what comes out of 19 Α. the HPA study and from the Danish work as well, that 20 21 they will extend these studies long enough to show one 22 way or the other. 23 Q. Yes. 24 Α. You could argue it's a bit late now. Everybody has 25 caught up and done look-back, even the Americans, but to

do a proper cost-effectiveness study you have to do
 that. You have to demonstrate benefit and then cost
 that benefit.

The next question that we asked you at the bottom 4 Q. Yes. of that page was what you thought had been achieved and 5 6 the answer is on the next page. I think one of the 7 major benefits you have identified is that the UK 8 transfusion services regained a measure of trust. Could 9 you just explain what you mean there, please? 10 I think I have already said there were various media Α. campaigns going on around the time when the decision was 11 12 taken to start and the headlines that appeared were 13 really quite toxic at times and damaging to the 14 reputation of the transfusion service, and none of us 15 stand to gain from the reputation of the transfusion 16 service being harmed.

17 So I think the fact that, although the delay was to 18 my mind unjustified and regrettable, it was turned round 19 very quickly and still was one of the very earliest 20 comprehensive look-backs in a large population, which 21 the UK is, worldwide. And I think that that was 22 important to calm down the atmosphere at the time and 23 show that really we took it on board, we did something 24 about it and we hope we have learned from it. And we 25 can demonstrate we have learned from it by our response

1 to CJD, HTLV-I and other problems that have cropped up 2 since then. Q. You have mentioned donor support. I imagine that that 3 is crucially important? 4 A. Absolutely, yes, and if donors see headlines criticising 5 6 the transfusion service, week in, week out, they are 7 going to question whether donating blood is something they want to do, and that's a disaster. 8 9 Yes. So you would see that in itself as an important Ο. reason for having done targeted look-back. Is that 10 right? 11 12 A. Well, it would have been better to have been preventive 13 rather than reactive but it's better to have reacted in 14 the right way rapidly, when we eventually accepted that 15 that's what had to be done. Q. Yes. The next question, final question, that we asked 16 17 was an important question: "What, if anything, would you have done differently 18 19 in hindsight?" 20 You say that you don't regret the stance that you 21 took on look-back and you don't think there is anything 22 that you could have done that would have hastened the 23 change in policy. Could you explain why you think that? 24 A. Well, I didn't really have a locus to change anything in any other way than doing what I did, which was stick to 25

1 my view that I thought we should do it and then go ahead 2 and do it and show what that resulted in. 3 Q. Yes. We asked you to comment on an article that you wrote "Look back on Hepatitis C look-back", and that's 4 at page 2 of [PEN0180822]. We see that that is under 5 the heading "Reader's Opinion": 6 7 "Look back on HCV look-back." 8 Can you just explain to us what the context of this 9 piece was, Dr Gillon? 10 Yes, this was the Journal of the International Society Α. of Blood Transfusion, of which Fereydoun Ala, who is the 11 12 director in Birmingham, was editor at the time. And 13 it's a magazine rather than a scientific journal. It's 14 disseminated worldwide, obviously to transfusion 15 services and -- I mean it's not a serious peer-reviewed journal or anything, and Fereydoun asked me to do this 16 17 short opinion piece, which I wasn't keen to do. 18 I really couldn't see the point in 1999. Was it 19 worthwhile? In a word, yes, and to fill the space I went on to speculate about why we hadn't done it 20 21 sooner. I see. Okay. Let's just have a look at the article. 22 Q. 23 I think you are taking an overview here of whether HCV 24 look-back was worthwhile and in the second column at the 25 top, the paragraph that starts "I think", you talk about

| 1  |    | a particular problem. I think if we could all just take |
|----|----|---|
| 2  |    | a minute to read from that paragraph to the end of the  |
| 3  |    | piece. So could I just ask you to read that again,      |
| 4  |    | Dr Gillon, just to yourself. (Pause)                    |
| 5  |    | Now that we have all had a chance to read that, you     |
| 6  |    | talk about the problem being one of psychology, rather  |
| 7  |    | than logic. I wonder if you could just explain to us    |
| 8  |    | what you mean by that?                                  |
| 9  | Α. | I think there was a bit of group-think that went on,    |
| 10 |    | actually. I think there may be something in this shying |
| 11 |    | away from the past and avoiding difficult things that   |
| 12 |    | might reflect badly on us. I just couldn't understand   |
| 13 |    | why my colleagues just didn't get on and do it,         |
| 14 |    | basically. I couldn't see what was apart from these     |
| 15 |    | minor resource issues, which I think were somewhat      |
| 16 |    | overplayed. And the only conclusion I can come to is    |
| 17 |    | that it was a group-think type of phenomenon, and once  |
| 18 |    | that gets established, it's very hard to turn round.    |
| 19 |    | I'm sure we have all had experience of that.            |
| 20 | Q. | The group-think would be, "Let's not do this because"   |
| 21 |    | well, as much as anything else, it's going to be an     |
| 22 |    | unpleasant exercise to carry out?                       |
| 23 | Α. | Yes, and it's unpleasant. It's a very difficult thing   |
| 24 |    | to grapple with. It's not just time-consuming, each     |
| 25 |    | case sort of rumbles on for a long team and it's very   |

1 hard to keep it all together. We started before there 2 were databases and computers to do this, and Excel 3 spreadsheets and what not. It was all bits of paper, massive bits of paper all taped together, with lists of 4 who had been contacted, where we had got to with this 5 one, that one, the other one. Very hard to 6 7 cross-reference, very hard to pick up the pieces when 8 a new piece of information came in. It really is not 9 fun to do. So anybody who had had any experience of 10 that would shy away from it obviously, and when there is a collective tendency to think that, it's very easy to 11 12 go along with it, I think.

13 Yes. I mean, as you put it the not fun aspect of it Q. 14 there that you are referring to is the logistics, the 15 difficulty of continuing to keep on top of it. But you also mention the fact that no one relishes the task of 16 17 telling patients that they were harmed by interventions 18 that were meant to help them. I imagine that that 19 exercise of counselling a patient and effectively telling the patient, that is something that no doctor 20 21 would really ever want to do, if they could choose? 22 No. It's the definition of "not fun". It's a very Α. 23 unpleasant thing to have to do.

Q. Do you think that was also a factor in the group-think?A. It may well have been. We were telling the donors -- we

1 had experience of giving people bad news, we had been 2 through it with HIV. If that was a reason, it shouldn't have been but as I say, nobody would look forward to 3 having to do it. 4 Q. Yes. Despite the fact that this was an opinion piece 5 6 that you didn't relish writing, does it still represent 7 your view? Yes, I think it does really, yes. 8 Α. 9 THE CHAIRMAN: Can I ask you this about the scheme: of the 10 nine people who were tested, found positive and who were still alive, do you know whether any of them did have 11 12 treatment as a result of that identification? 13 A. Not during the time when I was following them up, which 14 would have been a relatively short time, and then 15 I referred them on to a hepatologist experienced in the 16 field. 17 THE CHAIRMAN: Yes, indeed. I don't know. I didn't get feedback from the clinics 18 Α. 19 that I referred them to in fact, saying this patient has 20 been treated and failed or was unsuccessful. Once I referred them, the communication was between the 21 22 clinic and the GP rather than me. I had no locus. So 23 I am afraid I can't answer that question. Of course, 24 our look-back didn't stop at that six month point and it 25 has been ongoing ever since, so it's not just nine

1 patients that we have experienced --

2 THE CHAIRMAN: I appreciate that. I was simply looking for some indication of a particular positive outcome that 3 might have resulted had you known about it. 4 A. That will come out of the work that Helen Harris and HPA 5 6 are doing, and I know that Peter Hayes, who is the 7 hepatologist who runs the HCV clinic in the Royal, has 8 already made use of that resource for research. 9 THE CHAIRMAN: I can't remember if Professor Haves said 10 anything about that. MR GARDINER: We will have to look back and see. 11 12 PROFESSOR JAMES: A targeted look-back. 13 THE CHAIRMAN: A targeted look-back on the evidence, yes. 14 MR GARDINER: If we go back to your statement, please, 15 Dr Gillon, there were two final, practical questions 16 that you have answered about how look-back was taken 17 forward and then if we could go over the page, the 18 question about how the procedures attached to the CMO 19 letter of 3 April 1995 were implemented in practice. 20 You cover that in that answer. 21 Dr Gillon, I don't have any more questions for you 22 about look-back but obviously you have had experience of 23 look-back, first of all HIV and then HCV, and I suppose 24 look-back in a way never ends. A. That's right. 25

1 Is there anything else that you would like to tell the Q. 2 Inquiry about your experience of look-back? 3 Α. I think we have pretty well covered it and I would only extend my observation about the way the patients respond 4 to recent experience with CJD, which we were very 5 nervous about because there were four cases of 6 7 transmission of CJD through transfusion and that 8 resulted in a sort of reverse look-back, if you like, 9 and putting donors off, but then it extended --10 a reverse look-back -- I hesitate to mention this but a reverse look-back, of course, if you identify the 11 12 donor who transmitted, then maybe it kicks off 13 a targeted look-back from that donor to the previous donations. And there was a decision made to do that 14 15 with absolutely no prospect of treatment for 16 a potentially very nasty disease, and the fact that 17 these -- I was going to say "patients", they are not patients yet in this sense, but their medical records 18 19 would have -- I can't remember the exact wording but "at 20 risk of BCJD, treat as public health risk" with, you 21 know, destroying instruments when you have to have your 22 teeth out whatever, and those patients didn't complain, 23 extraordinarily. They accepted that information, which 24 I think is an indication that, if you turn the ethics 25 round and look at it from the patient's point of view,

1 which, of course, is the point of view you should be 2 taking, they think they should have the information. They don't resent it and don't say, "You shouldn't have 3 told me". And I think that is an ultimate ethics test 4 for what we have been doing. 5 Yes. Thank you very much. 6 Ο. 7 I don't have any more questions, sir. THE CHAIRMAN: Mr Di Rollo? 8 9 PROFESSOR JAMES: Could I ask one thing, please? This is 10 about the estimate that's in your 1994 paper, that you think that roughly, in Scotland, there would be around 11 12 about 150 individuals who would have been, as an 13 extrapolation from the data that you produced at that time, alive and who would have been infected at that 14 15 time. You and I have discussed the fact that as a matter of fact, in the year before you started your 16 17 look-back in Southeast Scotland, the criteria for 18 acceptance or the discouragement of potential donors who 19 might think that they might be at risk, was increased by 20 information leaflets and so on and, of course, we know 21 in the Inquiry that for the preceding eight or nine 22 years, largely consequent upon HIV testing and 23 discouraging donors from coming forward who might be HIV 24 positive, the proportion of individuals who are 25 HCV-positive would have decreased really very

1 significantly.

2 So I'm concerned that it has been used in some places, your estimate of only 150 "in Scotland", and you 3 are aware that, for example, Dr Soldan, who works or 4 worked with Dr Harris, produced some other modelling 5 estimates, which would be very considerably higher than 6 7 that. I don't think it's published but her estimate for 8 Scotland, which she gave to SEBTS, was probably in the 9 range of about 2,000 and for the UK was probably in the range of, from memory, 20,000 plus. 10

So we don't get this rather small 150 sort of in our minds too much, I wonder if you could comment on what I have just said.

14 A. Certainly. I think that's a very important point and 15 I'm very aware that those figures are out there of the 16 highest -- to my mind the highest -- to anybody's mind 17 surely, they would be alarming figures.

18 I would make two points, I think, really. One, 19 first of all, it depends crucially on how many infected 20 donors were coming through the door year on year up to 21 the onset of testing, and in my view the estimates in 22 those papers were too high and we have been working with 23 Professor Goldberg for the Inquiry, as you know, to try 24 to come up with a model for Scotland that better 25 reflects what actually happened and was happening in the

population in respect of Hepatitis C, and how that might have translated into the numbers of blood donors who were allowed to donate.

In other words, we have built in the factors that you mention, from donor selection in particular, but other factors about the changing prevalence, the sort of dynamics of the prevalence in the population, which is largely related to the drug using population in Scotland on which David Goldberg and his colleagues have done a huge amount of work.

11 I'm not sure if the Inquiry has seen any draft of 12 that latest paper but I have seen it in draft and the 13 numbers are much smaller than projected by Kate Soldan 14 and colleagues.

15 PROFESSOR JAMES: I think it has been requested and some 16 summary of it has been produced but the summary was 17 effectively written on the back of a postage stamp, and 18 I think the Inquiry would be very grateful to receive 19 Professor Goldberg's fuller examination. Perhaps 20 I could briefly just comment on that, which is that in 21 your own paper, the 1994 paper, you noted that half 22 a dozen of those nine had had transient IV drug 23 exposure, sort of a mean -- just glancing at them -- of 24 12 or 13 years previously. So that suggests that 25 actually at risk behaviour was going on, you know, in

1980, 1981, 1978 and so on and I think one should be
 very careful indeed of just allowing this 150 to float
 in the air. Do you see --

I sympathise with that and the other point I would make 4 Α. is that the look-back, even our look-back, which started 5 online, was starting 10/15 years after the risk activity 6 7 and a lot of the patients will have died by then. So 8 what we are finding is not that many patients alive and 9 infected, but that's not to deny that a much larger 10 number of patients were exposed, and extending back from that, that a very large number of blood components over 11 12 the years might have had Hepatitis C in them.

What we have also been able to show is that particularly in Scotland, where we were driven by the need to maintain plasma self-sufficiency, and that resulted in a huge outdating of red cells in particular in the mid 1980s, a lot of those components were never transfused.

19 PROFESSOR JAMES: Thank you very much, sir.

THE CHAIRMAN: Can I just enter one word of caution, that gratitude for Professor Goldberg's work is likely to suffer exponential decay as the process of writing the report continues and would eventually disappear if we didn't get it in good time.

25 Mr Di Rollo?

## Questions by MR DI ROLLO

1

2 MR DI ROLLO: Sir, I just want to ask Dr Gillon one point about the stance that Professor Cash took. 3 You have indicated, I think very clearly, that you 4 strongly disagreed with the stance that was taken at the 5 time, and obviously your actions speak louder than words 6 7 because you went off and did what you did. 8 What you have indicated, I think, in your evidence 9 is that it was for you a question of an ethical view, 10 and my learned friend referred to "look back on look-back", you say at the end of your article: 11 12 "These aspects, however, must not be allowed to 13 cloud the essential ethical issue, which is about the 14 responsibility of an individual doctor to an individual 15 patient." 16 I just want to ask: the reason for your strong 17 disagreement, to the stance that was taken by 18 Professor Cash, is it an ethical issue. Can you just 19 explain how you saw the ethical position at that time? A. Yes. I saw it very clearly as a dilemma about what to 20 21 do about a piece of paper landing on my desk with 22 a result which says "donation [such and such], confirmed 23 HCV-positive", and by the following day I would have the 24 donor's record on my desk with that information, showing 25 that there were previous donations, and that, to my

1 mind, translated into previous recipients and I couldn't 2 in all conscience ignore that information. So I saw it as my duty of care to the recipients of that blood that 3 their clinicians should have that information. 4 Is that irrespective of the fact that treatment may or 5 Q. may not be available for those individuals? 6 7 Α. Yes, obviously it is given more impetus if there is 8 treatment available but I would point out there was no 9 treatment available for HIV when we started doing that. 10 It was seen as a much more serious disease, and that may be arguable, but at the time that was the perspective, 11 12 and that it was a much more serious public health 13 problem. And again, that may be arguable in retrospect, 14 but even allowing for that, we did go into HIV look-back 15 without specific treatment. 16 Q. Thank you. 17 THE CHAIRMAN: Mr Anderson? Questions by MR ANDERSON 18 19 MR ANDERSON: Dr Gillon, Mr Di Rollo just now used the 20 phrase "the stance taken by Professor Cash". I wonder 21 if I can ask about that. After you had started your 22 look-back exercise in September 1991, which became 23 thereafter known as the "pilot study", whenever it was 24 that Professor Cash discovered what you were doing, did 25 he ever suggest to you that you must stop this, or that

1 you mustn't do it or whatever?

2 A. No, not at all.

3 Q. In his evidence to the Inquiry, David McIntosh, in
4 relation to the policy of look-back, described
5 Professor Cash as:

6 "... fighting a rear guard action to stop
7 implementation of look-back when it couldn't be done
8 universally in the UK."

9 He went on to say he was trying to stop it. Do you 10 think that's right?

A. No, I don't think he was trying to stop it. We have certainly got no evidence that he was trying to stop it as such and in fact, as we have seen, he and the MSC agreed with the policy and put it forward to the UK committees.

I mean, he was obviously very keen that it should be A UK-wide thing but he certainly didn't try to stop me and I didn't hear him or read anything from him that suggested he was trying to stop it in any active sense.
Q. Thank you very much.

21 MR JOHNSTON: Nothing from me, sir, thank you.

22 Further questions by MR GARDINER

23 MR GARDINER: Can I just clarify one thing with Dr Gillon?
24 THE CHAIRMAN: Yes.

25 MR GARDINER: My learned friend, Mr Di Rollo, asked you

1 about the look-back and you mentioned HIV look-back. 2 I was just wondering if you would accept that there was and is a difference in the infectivity of the two 3 diseases, and whether that would also be a factor in 4 doing look-back, you know, finding recipients of 5 6 donations that had been infected to, from a public 7 health point of view, avoid further spread of the disease? 8

9 Α. From the point of view of avoiding secondary spread? 10 Yes. I think there is a degree of difference in infectivity and there was a lot of doubt about the exact 11 12 extent of sexual transmission with Hepatitis C, but by 13 the time we wrote our report, I think we were writing 14 correctly that sexual transmission does occur, not 15 efficient and not as bad as with HIV and nowhere near as with Hepatitis B, which is very much more infectious. 16 17 But nevertheless it was there.

But, yes, I think there was a different perception;
it was seen as less serious, less infectious and less of
a risk to the community at large.

21 Q. I mean, the two diagnoses for the two diseases at that 22 time were very different in terms of health

23 implications?

24 A. Yes, I would accept that.

25 Q. Yes. Thank you very much.

1 THE CHAIRMAN: Dr Gillon, thank you very much indeed. 2 A. Thank you. (1.07 pm) 3 (The short adjournment) 4 (2.00 pm) 5 6 DR AILEEN KEEL (sworn) 7 Questions by MR GARDINER THE CHAIRMAN: Mr Gardiner? 8 9 MR GARDINER: Thank you, sir. 10 Good afternoon, Dr Keel. A. Good afternoon. 11 12 Q. The topic that we are considering in this section of the 13 Inquiry is the topic of C5, which is to do with tracing 14 and testing of patients, and we are particularly 15 interested in at the moment in look-back. You have very kindly provided the Inquiry with a statement in response 16 17 to certain questions. Is that right? A. Yes. 18 19 Q. Thank you. So could we have a look at your statement, 20 which is [PEN0180396]. I think you have a hard copy in front of you. 21 22 What's your current position, Dr Keel? 23 Α. I'm Deputy Chief Medical Officer for Scotland. 24 Q. Yes. What did you do before you joined the SHHD? A. I trained in haematology and was working as a consultant 25

1 in London immediately prior to coming back to Scotland 2 to the job as a Senior Medical Officer in SHHD. Yes. I think we have a copy of your CV, which is at 3 Q. PEN0180383. So this is a brief curriculum vitae? 4 5 Α. Yes. If you go to the second page, please. Honorary 6 Q. 7 Consultant Haematologist, Royal Infirmary of Edinburgh. 8 If we could go down, we see the heading "Professional 9 Qualifications/Membership", could you just take us 10 through those please? The MBChB is the basic medical degree. MRCP is 11 Α. 12 membership of the Royal College of Physicians. MRCpath 13 is membership of the College of Pathologists. The next 14 two are fellowships at the Glasgow College and the 15 College of Pathologists respectively. In 2004 I was awarded membership of the Faculty of Public Health in 16 17 recognition of the job that I had been doing, and in 2006 I was made a fellow of the Royal College of 18 19 Physicians of Edinburgh. Thank you. Could you give us your career resume, 20 Q. 21 please? As it says on the screen, I trained in general medicine 22 Α. 23 first of all and then in 1979 went up to Aberdeen to 24 begin training in haematology and progressed through 25 various jobs, sat the exam and qualified as

1 a consultant.

2 Q. Yes.

| 3  | Α. | Then in 1992 moved back to Edinburgh and to a job in the |
|----|----|--|
| 4  |    | Civil Service and was promoted to Principal Medical      |
| 5  |    | Officer in 19 gosh, I can't remember 1998 and then       |
| 6  |    | in 1999 was promoted to Deputy Chief Medical Officer,    |
| 7  |    | and I have been in that job ever since.                  |
| 8  | Q. | Yes. On the second page we see a list of your previous   |
| 9  |    | appointments.  |
| 10 | A. | Yes.   |
| 11 | Q. | So between 1987 and 1989, Consultant Haematologist and   |
| 12 |    | director of pathology, Cromwell Hospital in London. Was  |
| 13 |    | that purely clinical?                                    |
| 14 | A. | I was well, in that post it was mainly running the       |
| 15 |    | laboratory, a multidisciplinary laboratory, but I also   |
| 16 |    | had that was a private hospital, so I was doing          |
| 17 |    | private practice in haematology as well.                 |
| 18 | Q. | Yes. So it was mainly laboratory-based, was it?          |
| 19 | A. | At the Cromwell but I was still doing a lot of clinical  |
| 20 |    | work. As you can see, there is overlap between that and  |
| 21 |    | the post above, of Honorary Consultant Haematologist at  |
| 22 |    | the Central Middlesex, and I also worked at the          |
| 23 |    | Middlesex in a clinical role.                            |
| 24 | Q. | Yes. Okay. Could we go a bit further down the page?      |
| 25 |    | We see before the Cromwell Hospital, various locum       |

1 posts, St Mary's Hospital, Middlesex Hospital, before 2 that registrar in haematology at the Royal Infirmary, Glasgow, and lecturer in medicine at the University of 3 Aberdeen between 1979 and June 1981. 4 A. Hm-mm. 5 Yes, thank you. Okay. I think we can back to the 6 Q. 7 statement now, please, [PEN0180396]. So paragraph 2 is 8 just really repeating what we have seen on your CV and 9 what you have just told us. I don't know, Dr Keel, if you have been following 10 the transcripts of the Inquiry? 11 12 Not religiously but I have read some of them. Α. 13 Yes. Did you read the recent transcript from Q. Professor Cash's evidence? 14 15 From yesterday? Α. 16 Q. Yes. 17 Α. I have read part of it. Q. Yes, okay, thank you. I don't know if you saw the bit 18 19 where I referred him to Lord Fraser's letter but I would 20 like to ask you to have a look at that. It's 21 [SNB0084848]. Have you had an opportunity to read this 22 recently? 23 Yes, I have got a hard copy in front of me. Α. 24 Q. We have seen it fairly recently and what I would like to 25 draw to your attention is the second paragraph, where

Lord Fraser is talking about a pilot research study,
 which he says:

3 "... has established that a look-back exercise for
4 Scottish patients would be feasible and practicable."
5 Then at the bottom of that paragraph he says that
6 a failure to implement look-back:

"... may result in a liability for loss or injury." 7 8 Then starting on the first page, in the last 9 paragraph on that page he refers to the Advisory 10 Committee for the Microbiological Safety of Blood and Tissue for Transplantation committee, the MSBT, and over 11 12 the page he talks about what their advice is, 13 recommending that guidance should be drawn up but this leaves unresolved the question of timing. 14

15 It's the next sentence which I would like to 16 concentrate on. He says:

17 "The advice which I have received from my medical 18 and legal staff is such that I consider it's no longer 19 a matter of policy but of legal liability, and that the 20 look-back should take place as soon as possible in 21 Scotland. I am informed that the SNBTS is ready to 22 carry out such an exercise ..."

Just before we go back and look at some of the documents from the past, Dr Keel, I just wondered if you could help us with the question -- it's fairly

1 obvious -- who decided at this point to proceed with
2 look-back in Scotland?

A. Well, the Minister ultimately decided, but he was given
advice by a variety of policy colleagues, myself on the
medical side, and clearly -- we had taken advice from
legal colleagues at that point as well. So collegiate
advice to the Minister.

Q. Yes. It's really just as Lord Fraser says in the
letter, that his decision has been taken on the basis of
advice from SHHD staff, if you like, medical and legal.
Is that a fair way of looking at it?

12 A. Yes, I mean -- I was the main medical adviser in this 13 area at this point. I wouldn't have given advice on 14 legal liability but I certainly gave advice as to the 15 medical/clinical aspects and, of course, my view was 16 informed by perhaps meetings that we will be coming to 17 shortly, that happened in the months preceding this 18 letter.

19 Q. Yes. So your view would have been informed by the20 advice that you were getting from the SNBTS?

A. Yes, particularly around the Southeast Scotland pilot study, which had demonstrated for the first time that a look-back in this area was feasible. Up until then part of the reason that it hadn't taken place was that it was just perceived to be logistically too difficult

and the pilot look-back in Edinburgh had demonstrated that it was feasible; it was difficult but it was feasible. So that totally changed the context in which we were having these discussions.

O. Yes. We have heard evidence about the Medical and 5 Scientific Committee, MSC, of the SNBTS. We have heard 6 7 evidence about the Advisory Committee for Virological Safety of Blood, the ACVSB, which then became the 8 9 Microbiological Safety of Blood and Tissue committee, so 10 the Metters committee, MSBT. Then separately we have heard about the Advisory Committee On 11 12 Transfusion-transmitted Infections.

13 In Lord Fraser's letter he is referring to one of 14 those Advisory Committees but notwithstanding their 15 advice, he is proceeding with look-back. I'm just 16 wondering to what extent SHHD staff or yourself would 17 have been relying on the advice from these two Advisory 18 Committees?

19 A. Well, MSBT was the principal UK Advisory Committee, 20 which was run out of the Department of Health and as you 21 have said, by the then DCMO down there, Jeremy Metters. 22 That was the committee that the health departments 23 collectively looked to for advice. The other committee 24 didn't have government representation on it. It was 25 a group of professional advisers, whose views were

1 clearly very important, but MSBT was the Health

2 Department's Advisory Committee and that would have been 3 the one that we would have looked to for a steer on this 4 look-back.

Q. Yes. Okay, thank you. Could we have a look at the
letter that the Inquiry sent you, which is [PEN0172511]?
This is the letter which contains the questions which
you answer in your statement. Is that right?

9 A. Yes.

10 Thank you. Could we go over the page? We see there Ο. that the Inquiry has included a schedule which sets out 11 12 the historical context, and if we could go down to the 13 bottom of the page, we start in 1990 with a description of events and the first thing that's mentioned is the 14 15 working party to advise on policies and procedures. 16 Could we go over the page? We note that the authors 17 advise that look-back should be instituted from the 18 onset of testing.

19 Then the next paragraph:

20 "The proposal for look-back underwent further 21 discussion by both SNBTS and NBTS directors and was 22 finally rejected after referral by the SNBTS, national 23 medical director to the Department of Health, London." 24 Could we have a look at [SNB0018934]? We see that 25 these are the minutes of the Advisory Committee on the

1 Virological Safety of Blood and it's the minutes of the 2 ninth meeting of 25 February 1991. So this is the Inquiry that became the MSBT, if you like. I don't know 3 if you have had a chance to look at these before, have 4 5 you? I may have. I mean, I have looked at lots of documents 6 Α. 7 but, of course, this pre-dates my appointment to 8 Scottish Government. So ... 9 I realise that. We see that the chairman is Dr Metters Ο. 10 and one of the observers is Dr McIntyre. 11 Α. Yes. 12 So could you remind us who Dr McIntyre was? Q. 13 Dr McIntyre was the Principal Medical Officer when Α. 14 I joined the department back in 1992, who had 15 responsibility for laboratories and blood transfusion, and when I was appointed, I took over these areas from 16 17 him. So he clearly was attending ACVSB in advance of my 18 appointment. 19 Yes. So if you had been in post at that point, you Q. 20 probably would have been at this meeting? 21 A. Yes, and indeed I attended a couple of meetings of ACVSB 22 before it morphed into MSBT. 23 Yes. No doubt, when you joined, you would have been Q. 24 briefed about previous meetings? 25 Α. I have no strong recollection of being briefed

specifically about ACVSB but probably Archie would have
 briefed me.

Q. Could we go to page 6 in that document? You see at the 3 top of the page, paragraph 14, it's recorded that: 4 5 "The committee discussed the problems of look-back 6 and recommended that it should not be undertaken as 7 a service, leaving the option for those carrying out research. However, all cases of post-transfusion 8 9 hepatitis should continue to be investigated." 10 So the Advisory Committee there seems to be saying that they are not advising ministers to pursue 11 12 look-back. Would you agree? 13 A. I would agree. Thank you. The next document I would like to show you 14 Q. 15 is [SGF0012163]. This is an SHHD memo from Dr McIntyre 16 to Mr Panton. Who was Mr Panton? 17 A. He was one of my policy colleagues, who reported to 18 George Tucker, who was the assistant principal at that 19 point. So Rab Panton would have been a key policy colleague in taking these matters forward. 20 21 Q. Yes. Have you seen this before? 22 A. I think I have. 23 Q. Yes. 24 Α. I can't be quite sure but I think I have. 25 Q. Yes. Well, if you want to take a moment to just remind

1 yourself. (Pause)

| 2  |    | So we see there that he is referring to a copy of        |
|----|----|--|
| 3  |    | recommendations for counselling of HCV seropositive      |
| 4  |    | donors. He says:   |
| 5  |    | "As you know, I'm particularly concerned about           |
| 6  |    | paragraph 3.4 at page 6, which states 'in the case of    |
| 7  |    | regular donors, the fate of previous donations is        |
| 8  |    | determined and look-back initiated in accordance with    |
| 9  |    | SNBTS policy'."  |
| 10 | A. | Can I ask what the date of this policy is?               |
| 11 | Q. | Sorry, it's at the bottom of the page.                   |
| 12 | A. | 10 July 1991.  |
| 13 | Q. | Yes, the minutes I have just shown you are February 1991 |
| 14 |    | and this is July 1991.                                   |
| 15 | Α. | Yes.   |
| 16 | Q. | So he seems to be talking about look-back here, would    |
| 17 |    | you agree?   |
| 18 | A. | Yes.   |
| 19 | Q. | And the third paragraph:                                 |
| 20 |    | "In the present state of knowledge, donors who are       |
| 21 |    | only HCV seropositive donors without evidence of antigen |
| 22 |    | may not be infectious. What purpose is served by going   |
| 23 |    | back. Will it cause the recipient of the blood (the      |
| 24 |    | 50 per cent who are still alive after two years)         |
| 25 |    | unnecessary worry and possibly distress?"                |

So he seems to be raising a question about whether
 it's a good idea. Do you agree?

3 A. Yes, I would.

4 Q. Then he says:

5 "In certain circumstances, it could also give rise 6 to litigation and it may be that you would wish to 7 discuss this particular point with our solicitors before 8 this policy is put into effect."

9 I'm just wondering, that seems to be a hint that 10 there is a concern that look-back might give rise to 11 litigation one way or the other. I'm just wondering 12 whether, when you joined the service, you thought that 13 was something that was being considered in the whole 14 context of look-back?

15 Well, clearly from Archie's minute, this is a concern of Α. 16 his. I can't honestly remember it being an issue that 17 was particularly stressed in our discussions around 18 Hepatitis C and the possibility of look-back. I think, 19 as I said earlier, the main memory I have is that 20 look-back wasn't considered feasible, that logistically 21 it would be too difficult to undertake, rather than any major concerns around litigation. 22

Q. Yes. Could we now go back to the schedule to Dr Keel's
letter, please? So in the chronology we are coming to
paragraph 6 at the top of the page and there is

1 a reference there to the look-back that had been 2 commenced in Edinburgh and Southeast Scotland regional transfusion, then we move to 1993 and by this stage you 3 have joined the service. 4 A. Yes. 5 That's right. Just to get the historical context, again 6 Q. 7 paragraph 7: "5 October 1993, Dr Cash wrote to the SNBTS 8 9 directors raising the issue of HCV look-back ... he intended to raise the matter at the ... MSC ... 10 "On 18 November 1993, Dr Cash wrote to Dr Gunson 11 12 informing him of ... discussions ..." 13 The next paragraph: 14 "The ACTTI ..." 15 Which is the Advisory Committee On 16 Transfusion-transmitted Infections: "... met on 18 January 1994 ..." 17 18 Could we go over the page: "Various members of the committee were to look into 19 20 the issue further and report back at the next meeting." 21 Then we come to 16 May 1994: 22 "An SNBTS issues meeting was held at St Andrew's 23 House." 24 We have the minutes of that at [SGH0040847]. Have 25 you had an opportunity to look at this, Dr Keel?

1 A. Yes, again I have a hard copy with me.

Q. Okay, thank you. We see that you are in attendance
 there.

4 A. Yes.

5 Q. What is an issues meeting?

Well, blood transfusion is an area that is never quiet. 6 Α. 7 There are always lots of things going on and I think, as 8 can be seen from other minutes around this area, Medical 9 and Scientific Committee minutes, for example, there are 10 a lot of various activities being undertaken by the transfusion centres, which give rise to issues which 11 12 government need to be aware of. So these meetings, 13 I think, were set up with a view to providing a forum for discussion of issues of mutual concern. 14

15 Q. Yes. So is it an ad hoc meeting in response to events? We have these meetings nowadays and we have them 16 Α. 17 regularly. Going back to 1994, my recollection is they 18 were more sporadic than they are now, but they weren't 19 just ad hoc; it was, I suppose, perhaps when policy 20 colleagues in particular felt there was enough on the 21 agenda to make a meeting worthwhile.

Q. Before we look at the detail of this meeting, can you remember, casting your mind back, from the time that you joined the service up until this point at the beginning of 1994, what was the general attitude at SHHD to

1

## implementing look-back in Scotland?

2 I think it was as I have already outlined, that we Α. shouldn't be proceeding with it because of the view that 3 it wouldn't be feasible and the other relevant point is 4 that at that point there was no really evidence-based 5 6 treatment which would be effective for individuals 7 identified with the virus. Treatments were beginning to 8 emerge around about this time but up until 1994, there 9 were no effective treatments.

10 Q. So shouldn't be proceeding because it wasn't thought to 11 be feasible and, number two, there wasn't any treatment 12 in any event?

13 A. Yes.

Yes. In reaching that view, to what extent did you and 14 Q. 15 your colleagues at SHHD rely on advice from the SNBTS? 16 Well, I think our view was informed by SNBTS's view, Α. 17 obviously, but more widely by the view which had been 18 expressed by committees south of the border, in 19 particular MSBT, over a period of time and also by 20 expert opinion, you know, across the UK and more widely 21 because there hadn't been any look-back exercise in any 22 other parts of the world, for example.

23 THE CHAIRMAN: Could I ask a question. Before this meeting 24 that we were coming to, did you know that there was 25 a study of the nature of look-back going on in Edinburgh

- 1 and the Southeast of Scotland?
- 2 A. I did not.

3 THE CHAIRMAN: You had no information about this at all?
4 A. No specific information. It may have been mentioned.
5 I would use the phrase "in passing" but I had no detail
6 of what was going on until the meeting of the Medical
7 and Scientific Committee of SNBTS on 18 May, which was
8 two days after this meeting.

9 THE CHAIRMAN: Information in passing can still spark 10 interest, Dr Keel. Do you have any recollection of 11 anything that did spark any interest in you in such an 12 event?

13 There had in late 1993 been a conference in the college Α. 14 in Edinburgh around Hepatitis C, which I attended, and 15 there was interest then in the emerging treatment, which was Alpha interferon. So, yes, I mean, obviously, I was 16 17 aware of this developing area and the idea that we might 18 at some point be able to offer treatment to patients, 19 although it was by no means 100 per cent recognised, even by experts, such as Harry Zuckerman, that Alpha 20 21 interferon was a particularly effective treatment.

22 So I suppose round about this time, yes, there were 23 various things happening, the conference that I have 24 mentioned being one of them. There was also a meeting 25 of the MSC in late November, where look-back was on the

1 agenda, but I have no clear recollection from that 2 meeting of any detail around the Southeast Scotland pilot, nor of any particular emphasis being given by 3 Professor Cash and his colleagues to the need to get on 4 and do this, and certainly there was no detail revealed 5 6 at that meeting of the Southeast Scotland pilot. That 7 did follow at the later meeting, on 18 May. THE CHAIRMAN: Yes. I'm sure that Mr Gardiner will want to 8 9 fill in a lot of this detail but do you have no 10 recollection of data from the pilot study being made available at the symposium? 11 12 No, I don't, no, I am afraid. Α. 13 THE CHAIRMAN: Mr Gardiner, I wanted just to go back 14 a little but I'll leave it to you to develop. 15 MR GARDINER: Yes. Let's go back to the symposium, if you 16 wouldn't mind, Dr Keel. Could we have a look at 17 [PEN0180553]? This is a flyer for the symposium "Hepatitis C virus infection". Does it ring any bells? 18 19 A. I know that I was there, yes. Yes. Could you go to the next page, 0554? We see on 20 Q. 21 the right-hand side the speakers, Dr Follett, 22 Dr Simmonds, Dr Gillon. 23 Α. Yes. 24 Q. I know it's a while ago but do you have any memory of 25 being present for the morning speakers?

| 1  | A. | Well, given that I attended, I imagine I was there in  |
|----|----|--|
| 2  |    | the morning but I have no recollection. I mean, these  |
| 3  |    | speakers, it looks from the titles that they have been |
| 4  |    | given that they are setting the scene for, you know,   |
| 5  |    | outlining the basic epidemiology, the tests that are   |
| 6  |    | available. So, no, I can't remember the presentations  |
| 7  |    | on my feet.  |
| 8  | Q. | Can you remember any of the speakers on that day?      |
| 9  | Α. | I remember Professor Dusheiko talking about treatment. |
| 10 |    | I imagine he is further down the                       |
| 11 | Q. | Yes, he was in the afternoon at 2 o'clock, we can see. |
| 12 | A. | Yes.   |
| 13 | Q. | But you don't have any memory, as you sit there today, |
| 14 |    | of Dr Gillon's talk?                                   |
| 15 | A. | No, and I'm interested that there is no mention of     |
| 16 |    | look-back in Jack's title.                             |
| 17 | Q. | Yes.   |
| 18 | Α. | So I would infer from that that he did not talk about  |
| 19 |    | the look-back but perhaps I'm wrong.                   |
| 20 | Q. | Well, Dr Gillon told us this morning that he did talk  |
| 21 |    | about his experience of look-back in the southeast and |
| 22 |    | he has actually provided a copy of the paper that he   |
| 23 |    | gave, although it was subsequently revised. I'll just  |
| 24 |    | let you have a look at that. It's at page 4 of         |
| 25 |    | [PEN0181420]. Actually could we go to page 2 first of  |

1 all? I appreciate that this is all new for you, 2 Dr Keel, and it's a long time ago but what Dr Gillon told us this morning is that this is the paper that he 3 spoke about. These are the things that he covered in 4 his talk. 5 6 So on the first page we see "Epidemiology of 7 Hepatitis C", "Historical perspective" and then 8 "Geography". If we go over the page, at the bottom of the page, just about two thirds of the way down, there 9 10 is a paragraph that begins: "In a small study ...." 11 12 If you could see that? 13 Yes, I can see that. Α. 14 If you want to just read from there to the bottom, just Q. 15 take your time to read that. (Pause) 16 A. Can I ask if this is an abstract that Jack produced 17 after the meeting perhaps, for publication, because I mean, he wouldn't have stood up and delivered this. 18 19 He would have used a Powerpoint presentation, I imagine. 20 Yes. Q. 21 With selected headings. Α. 22 Yes, well, I don't think he was suggesting that the text Q. 23 of his talk was given out and also he told us that it 24 was revised subsequently to a certain extent, footnotes 25 were inserted and so on. But he did tell us that at his

1 talk he presented this data to the audience.

| 2  | A.       | Well, I have no recollection of that part or any part  |
|--|----------|--|
| 3  |          | of his presentation, I am afraid. I mean, if I could   |
| 4  |          | just comment, it doesn't say "in a look-back in  |
| 5  |          | Southeast Scotland", it says "in a small study", so the  |
| 6  |          | term "look-back" isn't even being used by him. If he   |
| 7  |          | had said "look-back" then maybe that would have lodged   |
| 8  |          | in my memory more than it clearly has.   |
| 9  | Q.       | Yes, I understand. You would accept that what he is  |
| 10   |          | describing there is looking back to the recipients of  |
| 11   |          | donated blood?   |
| 12   | Α.       | Indeed, yes.   |
| 13   | Q.       | So he is clearly describing a look-back exercise. Would  |
| 1 /  |          |  |
| 14   |          | you agree?   |
| 14   | Α.       | you agree?<br>Yes.   |
|  | A.<br>Q. |  |
| 15   |          | Yes.   |
| 15<br>16                                     |          | Yes.<br>Thank you. We got sidetracked there. Could we go back  |
| 15<br>16<br>17                               |          | Yes.<br>Thank you. We got sidetracked there. Could we go back<br>to <u>[SGH0040847]</u> ? Could we go to 0849? We see there  |
| 15<br>16<br>17<br>18                         |          | Yes.<br>Thank you. We got sidetracked there. Could we go back<br>to <u>[SGH0040847]</u> ? Could we go to 0849? We see there<br>under the heading "Hepatitis C look-back":  |
| 15<br>16<br>17<br>18<br>19                   |          | Yes.<br>Thank you. We got sidetracked there. Could we go back<br>to <u>[SGH0040847]</u> ? Could we go to 0849? We see there<br>under the heading "Hepatitis C look-back":<br>"Mr McIntosh indicated that when Hep C testing of   |
| 15<br>16<br>17<br>18<br>19<br>20             |          | Yes.<br>Thank you. We got sidetracked there. Could we go back<br>to <u>[SGH0040847]</u> ? Could we go to 0849? We see there<br>under the heading "Hepatitis C look-back":<br>"Mr McIntosh indicated that when Hep C testing of<br>donations was introduced in 1991 it was not thought  |
| 15<br>16<br>17<br>18<br>19<br>20<br>21       |          | Yes.<br>Thank you. We got sidetracked there. Could we go back<br>to <u>[SGH0040847]</u> ? Could we go to 0849? We see there<br>under the heading "Hepatitis C look-back":<br>"Mr McIntosh indicated that when Hep C testing of<br>donations was introduced in 1991 it was not thought<br>appropriate to look back over previous donations.   |
| 15<br>16<br>17<br>18<br>19<br>20<br>21<br>22 |          | Yes.<br>Thank you. We got sidetracked there. Could we go back<br>to [SGH0040847]? Could we go to 0849? We see there<br>under the heading "Hepatitis C look-back":<br>"Mr McIntosh indicated that when Hep C testing of<br>donations was introduced in 1991 it was not thought<br>appropriate to look back over previous donations.<br>Mr Panton confirmed that any claims for compensation |

department for clearance. This would then be used in response to any newspaper/media enquiries received by SNBTS."

So the first question, Dr Keel, is: do you think
that it was at this meeting that you first became aware
of the Dr Gillon data about look-back?

A. My clearest recollection of Jack Gillon's work was at
the meeting two days after this at the MSC. In relation
to this meeting, I really have no strong recollection of
the discussion around the look-back. Clearly it was
discussed. But the meeting two days later had a much
bigger impact on me.

Q. Yes. We are going to come to that. But the other thing I wanted to ask you about was Mr Panton referring to claims for compensation in the context of look-back, and I'm just wondering again, does this represent a concern that was about in the SHHD at that time, that proceeding with look-back could precipitate claims?

19 A. I can only repeat what I said earlier in answer to this 20 question: to me it was not a major element in our 21 thinking around why look-back should not go ahead. That 22 related to the other factors that I have already

23 outlined.

Q. Yes. The other thing I wanted to ask you about was thisreference to newspaper and media enquiries. Would we be

1 correct in getting the impression that at this point the 2 media/newspapers are becoming interested in the question of look-back? 3 A. Well, that sentence would certainly give that impression 4 but I'm not quite clear why that should have been at 5 6 this particular juncture, that there should have been 7 media interest, just de novo. So I don't quite 8 understand where the media interest might have been 9 coming from or why it had been stimulated. Do you have a memory at that point of media interest in 10 Ο. the look-back question? 11 12 Not at this point, no. Α. 13 Thank you. So do we take it then that when you left Ο. 14 this meeting, you didn't think that look-back was 15 a particularly hot issue? 16 I think that would be a fair thing to say, yes. Α. 17 Q. Okay. Thank you. Could we go to the 18 May minutes, which are [SNB0099331]? We see present Professor Cash, 18 19 Dr Gillon, yourself, Dr Mitchell, Dr McClelland, 20 Dr Perry, Mrs Thornton. First of all, Dr Keel, could 21 I just ask: was it normal for you to attend MSC 22 meetings? 23 My recollection is that it was normal. I wouldn't Α. 24 perhaps be there for the whole event but I would attend for part of the meeting, depending on other diary 25

1 commitments.

25

| 2  | Q. | Yes. How would you decide which bits of the meeting you  |
|----|----|--|
| 3  |    | would stay for and which bits you wouldn't be present    |
| 4  |    | for?   |
| 5  | A. | I suppose I would look at the agenda in advance but      |
| 6  |    | I think more often than not I tried to be there at the   |
| 7  |    | beginning and stay for as long as I could.               |
| 8  | Q. | Yes. Professor Cash told us, I think I'm right in        |
| 9  |    | saying, that he had specifically arranged for you to     |
| 10 |    | attend this meeting because look-back was going to be    |
| 11 |    | discussed and he thought it would be important for you   |
| 12 |    | to be there. Does that ring any bells with you?          |
| 13 | A. | No, I read that in Professor Cash's evidence yesterday   |
| 14 |    | and that doesn't tally with my recollection of fairly    |
| 15 |    | routine attendance at these meetings. I certainly have   |
| 16 |    | no recollection of him approaching me and saying,        |
| 17 |    | "Look-back is going to be on the agenda, you need to be  |
| 18 |    | there".  |
| 19 | Q. | Yes. Hypothetically, if that had been the case and you   |
| 20 |    | had known that look-back was going to be discussed, what |
| 21 |    | would you have seen as your role at the meeting?         |
| 22 | A. | Well, I suppose it would have depended on whether John   |
| 23 |    | or SNBTS had told me they wanted to go ahead with a      |
| 24 |    | look-back exercise. Had that been the case, I would      |

definitely have spoken to policy colleagues before I set

off for the meeting.
 Q. Yes. Why was that? Why was that whet it is the second sec

| 2   | Q. | Yes. Why was that? Why would that have been? If you      |
|-----|----|--|
| 3   |    | had been getting that advice, why would you need to      |
| 4   |    | speak to policy colleagues?                              |
| 5   | A. | Well, because this would have been a change in view on   |
| 6   |    | look-back. We have had a lengthy discussion up until     |
| 7   |    | now about the reasons why Scottish Government and other  |
| 8   |    | bits of the UK Government didn't want to proceed with    |
| 9   |    | look-back. So that was the policy which was in my mind.  |
| 10  |    | So if I had been given advance notice that SNBTS were    |
| 11  |    | going to present me with evidence that suggested we      |
| 12  |    | should be moving towards a look-back, then I would       |
| 13  |    | have well, it would have been obvious that I should      |
| 14  |    | have discussed it with policy colleagues because no      |
| 15  |    | decision in government is ever taken unilaterally; it's  |
| 16  |    | always, as I said earlier, a corporate decision and      |
| 17  |    | advice is developed by a number of people before we go   |
| 18  |    | to ministers.  |
| 19  | Q. | Yes. So, to the best of your recollection, you arrived   |
| 20  |    | at the meeting thinking SHHD policy is we are not going  |
| 21  |    | ahead with look-back, but if you received advice from    |
| 22  |    | the SNBTS, which would be advising that look-back should |
| 23  |    | be proceeded with, then that would be a change of policy |
| 24  |    | and so you would want to check first with colleagues     |
| 0.5 |    |  |

25 about that?

| 1  | Α. | Yes, and I think that's the way that the meeting is      |
|----|----|--|
| 2  |    | minuted. Obviously, if there is new evidence, then that  |
| 3  |    | has to be taken into account in terms of developing      |
| 4  |    | policy and possibly changing it.                         |
| 5  | Q. | Yes. I mean, am I right in thinking that it would still  |
| 6  |    | be ultimately a question for SHHD to decide on the basis |
| 7  |    | of that new evidence whether to change policy?           |
| 8  | Α. | Well, I think I know where this is heading because the   |
| 9  |    | minutes clearly indicate that I suggested that it might  |
| 10 |    | not be a matter for SHHD and the reason behind that      |
| 11 |    | is I think that the words I expressed a view that:       |
| 12 |    | "SHHD may not have a locus in this matter and the        |
| 13 |    | SNBTS should make a decision on look-back for HCV that   |
| 14 |    | was based on their professional judgment."               |
| 15 |    | The minutes are perhaps not as explicit as they          |
| 16 |    | might be but I think what I was trying to convey to      |
| 17 |    | SNBTS was that if in their professional by that          |
| 18 |    | I meant clinical judgment, a look-back was feasible,     |
| 19 |    | as Jack Gillon had clearly demonstrated, then they,      |
| 20 |    | because they have a duty of care to donors and           |
| 21 |    | recipients of blood, might feel the necessity to proceed |
| 22 |    | with it on professional grounds.                         |
| 23 |    | You have to remember that I was a relatively new         |
| 24 |    | recruit to government at that point. I knew that         |

25 I unilaterally should not be taking any decisions in

this area about changes in policy and, as is clearly
 minuted, I said I would like to discuss it back at base
 with colleagues before SNBTS did anything.

And what isn't minuted here is the fact that Jack Gillon gave a presentation at this meeting, which for the first time -- well, the first time that I remember -- very explicitly laid out how they had gone about it, how many people they had identified and how successful they had been, in a limited way, in tracing recipients of blood, blood components.

11 So at that meeting, as I say, I was really conscious 12 in a very powerful way of what had been going on, which 13 had not been visible to us, certainly not overtly, prior 14 to that. So this was absolutely, as far as I was 15 concerned, new evidence that I needed to discuss with 16 colleagues. But I felt that this was really a clinical 17 judgment as to whether to go ahead with it.

18 Now, clearly, SNBTS needed help with organising it 19 and the look-back exercise was announced by the Chief Medical Officer, by the Secretary of State, and all of 20 21 that had to be behind it to make it a success but in 22 purely professional terms, they had identified that they 23 could do it, that they were identifying recipients of 24 blood that was infected and therefore they had a duty of 25 care to those individuals. So that was why I said what

1 I said.

2 Yes. Just to take it step by step, Dr Keel, without Ο. 3 looking at what was discussed at the meeting, just to be clear about what you thought the position was when you 4 arrived at the meeting, was it that SHHD policy was, no 5 look-back, and would only be changed or may be changed 6 7 if new evidence was presented by the SNBTS? Or was it 8 that SHHD policy was no look-back but that policy could 9 be changed by SNBTS advising you that in their clinical 10 judgment, you should go ahead with look-back? Do you see the distinction? Whose decision is it ultimately? 11 12 Is it the SNBTS? If they say, "You go ahead", and you 13 have to go ahead, or they present this new evidence and 14 you take account of that and then make the decision? 15 Well, probably the former is the way that, you know, the Α. 16 process should work. I mean, the way it's minuted, 17 I come over as perhaps conveying the idea that this is 18 SNBTS's decision and that may reflect the fact that 19 I had not been the Senior Medical Officer for all that 20 long at that point. But I come back to the fact that 21 I said very clearly, "I need to discuss this with 22 colleagues," and that is minuted. And indeed, I left 23 the meeting and went straight back to St Andrew's House 24 to speak to Rab Panton.

25 Q. So just before the meeting, just to be clear, are you

saying that it wasn't a decision for SNBTS; it was still
a decision for SHHD?

A. Well, it wasn't at that point because SNBTS hadn't 3 presented us with this new evidence, which, as I say, 4 changed the entire context of the debate around should 5 6 there or should there not be a look-back exercise. 7 Government policy is always informed by information from 8 various sources and in this situation SNBTS clearly were 9 a key source of information and provided evidence that 10 the context had changed because they had demonstrated that the look-back was feasible. 11

12 Q. Yes.

13 A. So that had to inform government policy and indeed it14 did.

15 Yes. But ultimately, no matter what happened at the Ο. 16 meeting, it was your view before you got there that it 17 was the SHHD's decision; it wasn't a question of the 18 SNBTS making the decision, it was still your decision? 19 A. Well, it would be a UK government decision ideally because the major Advisory Committee, MSBT, was set up 20 21 to advise all four UK governments at that point. So 22 I would have been aware of that at the back of my head. 23 So, yes, it would not have been SNBTS's decision to 24 proceed unilaterally with a look-back.

25 THE CHAIRMAN: Mr Gardiner, can you keep an eye on the time?

1 MR GARDINER: Yes, indeed.

| 2  |          | Let's have a look at what's in the minutes? Could   |
|--|----------|---|
| 3  |          | we go to 9335? You have had an opportunity to read  |
| 4  |          | these minutes. That's right, isn't it, Dr Keel?   |
| 5  | Α.       | Yes.  |
| 6  | Q.       | Under "Any other competent business":   |
| 7  |          | "HCV look-back.   |
| 8  |          | "This very complex and extremely important issue was  |
| 9  |          | discussed at length. The committee unanimously agreed   |
| 10   |          | that on finding a 'known' (or regular) donor who was now  |
| 11   |          | anti-HCV-positive, the SNBTS should"  |
| 12   |          | Then on the next page we have (i), (ii), (iii) and  |
| 13   |          | (iv). That really describes look-back, would you agree?   |
|  |          |   |
| 14   | A.       | Yes.  |
| 14<br>15                                     |          | Yes.<br>So the committee is suggesting that look-back should be   |
|  |          |   |
| 15   | Q.       | So the committee is suggesting that look-back should be   |
| 15<br>16                                     | Q.       | So the committee is suggesting that look-back should be pursued. That's correct, isn't it?  |
| 15<br>16<br>17                               | Q.       | So the committee is suggesting that look-back should be<br>pursued. That's correct, isn't it?<br>Well, as I say, what's missing from these minutes is the   |
| 15<br>16<br>17<br>18                         | Q.       | So the committee is suggesting that look-back should be<br>pursued. That's correct, isn't it?<br>Well, as I say, what's missing from these minutes is the<br>fact that Jack Gillon gave a presentation. So the  |
| 15<br>16<br>17<br>18<br>19                   | Q.       | So the committee is suggesting that look-back should be<br>pursued. That's correct, isn't it?<br>Well, as I say, what's missing from these minutes is the<br>fact that Jack Gillon gave a presentation. So the<br>committee's views would have been formed on the basis of  |
| 15<br>16<br>17<br>18<br>19<br>20             | Q.       | So the committee is suggesting that look-back should be<br>pursued. That's correct, isn't it?<br>Well, as I say, what's missing from these minutes is the<br>fact that Jack Gillon gave a presentation. So the<br>committee's views would have been formed on the basis of<br>the evidence that he presented. So the committee was  |
| 15<br>16<br>17<br>18<br>19<br>20<br>21       | Q.<br>A. | So the committee is suggesting that look-back should be<br>pursued. That's correct, isn't it?<br>Well, as I say, what's missing from these minutes is the<br>fact that Jack Gillon gave a presentation. So the<br>committee's views would have been formed on the basis of<br>the evidence that he presented. So the committee was<br>expressing the view that look-back should proceed.  |
| 15<br>16<br>17<br>18<br>19<br>20<br>21<br>22 | Q.<br>A. | So the committee is suggesting that look-back should be<br>pursued. That's correct, isn't it?<br>Well, as I say, what's missing from these minutes is the<br>fact that Jack Gillon gave a presentation. So the<br>committee's views would have been formed on the basis of<br>the evidence that he presented. So the committee was<br>expressing the view that look-back should proceed.<br>Would you consider yourself to be a member of the |

1 A. No, that's not me.

| 2  | Q.  | I'm sorry, I have not given you a chance to tell us     |
|----|-----|---|
| 3  |     | about Dr Gillon's presentation. Would you like to tell  |
| 4  |     | us about that?  |
| 5  | A.  | Well, my recollection and it's a long time ago but my   |
| 6  |     | recollection is of Jack standing up and showing various |
| 7  |     | slides on how they had gone about the pilot and         |
| 8  |     | providing to me, and clearly to the other people round  |
| 9  |     | that table, convincing evidence of the feasibility of   |
| 10 |     | undertaking this exercise and of tracing infected       |
| 11 |     | donations to recipients.                                |
| 12 | Q.  | Yes.  |
| 13 | Α.  | It made a powerful impression on me.                    |
| 14 | Q.  | Yes. The message was: look-back is feasible.            |
| 15 | Α.  | Yes.  |
| 16 | MR  | GARDINER: Sir, I think that might be a good moment.     |
| 17 | THE | CHAIRMAN: I think so.                                   |
| 18 |     | We have to allow the stenographer time to recover,      |
| 19 |     | Dr Keel.  |
| 20 | (3. | 04 pm)  |
| 21 |     | (Short break)   |
| 22 | (3. | 21 pm)  |
| 23 | THE | CHAIRMAN: Yes, Mr Gardiner?                             |
| 24 | MR  | GARDINER: Thank you, sir.                               |
| 25 |     | Dr Keel, could we go back to the minutes that we        |

1 were looking at beforehand. This is on page 9336. We 2 have just looked at the bit where the committee is 3 recommending look-back and then at paragraph 5 it says: "From an SHHD perspective, AK expressed a view that 4 the SHHD may not have a locus in this matter." 5 6 I take it that "matter" there is referring to the 7 question of whether to proceed with look-back. 8 Α. Yes. 9 Q. Okay. Please correct me if I'm wrong but I'm just 10 surmising from your previous evidence that you would probably accept now that SHHD did have a locus in that 11 12 matter and if that's correctly recorded there, about 13 what you said, then it's maybe just because you were 14 relatively new in your post. Is that right? 15 Yes, I would accept that. Α. Yes. Okay. So just reading on: 16 Q. 17 "... SNBTS should make a decision on look-back for 18 HCV and that was based on their professional judgment. 19 However, before SNBTS took any action, AK asked to be 20 given the opportunity to discuss the issues with SHHD 21 colleagues to seek their views and ask that the SNBTS 22 take no formal action until she had subsequently 23 contacted JDC." 24 Then: 25 "Once AK had communicated the SHHD position to JDC

1 and provided SHHD were in agreement that the SNBTS 2 should implement this policy, JDC would write to [David McIntosh] to provide details of the SNBTS policy, 3 thereby allowing a decision to be taken on a starting 4 date for the process. JDC would also formally advise 5 NBA, NIBTS, SACTTI and MSBT of the SNBTS policy." 6 7 Are the minutes accurate, as far as you can remember, about what was discussed? 8 9 Α. I honestly can't recall this part of the discussion. As 10 I said before, we stopped for tea, Jack Gillon's presentation is the thing that I remember most clearly 11 12 because it made a powerful impact on me and convinced me 13 as a clinician that this was the right thing to be 14 doing. I don't think even in my then current relative 15 newcomer state I would have accepted that John Cash would inform MSBT of a change in policy of this 16 17 magnitude. So I don't think I wouldn't agree with that bit of the minute. 18 He is saying changes of SNBTS policy. 19 Q. Yes, but even so, I would have expected him to use the 20 Α. 21 department or indeed one of the SNBTS members of MSBT to 22 convey the SNBTS change in view in this area, rather 23 than him doing it directly. Q. Yes. 24

25 A. So I honestly don't know whether that is accurate, but

| 1  |    | clearly MSBT was not a committee on which he sat and     |
|----|----|--|
| 2  |    | therefore it would not have been appropriate for him to  |
| 3  |    | be conveying any view to them.                           |
| 4  | Q. | Even if he is expressing the view of the SNBTS?          |
| 5  | A. | MSBT was the vehicle of the government health            |
| 6  |    | departments. I was sitting round this table, being part  |
| 7  |    | of this discussion. So I think perhaps John would have   |
| 8  |    | expected me or my colleagues to convey that view to MSBT |
| 9  |    | that SNBTS had come up with this new evidence.           |
| 10 | Q. | Yes. Then just reading on, we see:                       |
| 11 |    | "If SHHD agreed that SNBTS should develop and            |
| 12 |    | implement a look-back policy for HCV, AK subsequently    |
| 13 |    | would communicate this to the [Department of Health]."   |
| 14 |    | That last bit, would you say that was an accurate        |
| 15 |    | note of what was agreed?                                 |
| 16 | A. | Yes, I mean, whether it was me as an individual or SHHD  |
| 17 |    | conveying this view to DH is a moot point. One way or    |
| 18 |    | another we would have had to let the Department of       |
| 19 |    | Health know about it. All of this was predicated on the  |
| 20 |    | discussion that I was going to have with my policy       |
| 21 |    | colleagues.  |
| 22 | Q. | Yes. Did you have that discussion after this meeting?    |
| 23 | A. | I did. I think the minutes say that I perhaps no.        |
| 24 |    | I left the meeting we broke for tea, I have              |
| 25 |    | a recollection of breaking for tea, probably around      |

1 about 3 o'clock, and I also have a recollection of 2 someone from SNBTS saying to me that John Cash was 3 phoning Harold Gunson to relay my views expressed in the 4 meeting and that SNBTS would be going ahead with the 5 look-back.

6 Well, at that point I thought I had better get my 7 skates on and get back up St Andrew's House and discuss 8 all of this with policy colleagues as a matter of 9 urgency, and as I said earlier, that's exactly what 10 I did because clearly John, for -- well, if the person who said that he was on the phone to Harold Gunson is 11 12 correct, John was rather jumping the gun on this. 13 What do you say he was representing to Dr Gunson about Q. 14 your position?

15 A. Well, this is hearsay because it's through a third party 16 but my recollection is that it was clearly conveyed to 17 me that John was saying Government, SHHD, had said they 18 could go ahead with the look-back.

19 Q. Right. So he was --

20 A. So it would be happening in Scotland.

Q. Right. So Professor Cash was representing that you, as representing SHHD, had said at the meeting that the SNBTS could go ahead with look-back?

A. Yes, that is my recollection of what was said to me atthe tea break during this MSC meeting.

1 Q. Yes. Professor Cash is on the phone to Dr Gunson and he 2 is saying that you are saying that they can go ahead with look-back? 3 A. Yes. 4 O. Yes. But that wasn't correct? 5 It certainly wasn't correct and the minutes reflect 6 Α. 7 that. Yes. But Dr Gillon's presentation had made a very big 8 Q. 9 impression on you? Indeed it had, and I was convinced as I left that 10 Α. meeting that whatever previous views of SHHD had been, 11 12 it was my job to convince policy colleagues that the 13 right thing to do now was to go ahead with the look-back 14 because Jack's pilot had demonstrated its feasibility. 15 Q. Yes. Because you personally had been persuaded? Indeed, I had been. 16 Α. 17 Ο. Yes. Which colleagues did you discuss this matter with? 18 Α. I think I went to see Rab Panton immediately. 19 I think -- again my recollection is rather hazy but 20 having told him the tale, I think we probably went along 21 to his senior, George Tucker, and I think we had 22 a collective discussion, but I can't be absolutely sure 23 about that but I certainly briefed Rab. 24 Q. Yes. So the message that you gave to Mr Panton was, 25 "I'm persuaded that we should be going ahead with

| 1  |    | look-back and we should be doing something about it."    |
|----|----|--|
| 2  | Α. | Yes.   |
| 3  | Q. | Okay. What was his reaction to that?                     |
| 4  | Α. | I don't have a very clear recollection but I'm sure he   |
| 5  |    | took what I was saying very seriously and I think        |
| 6  |    | I would also have said to him, "And by the way, I think  |
| 7  |    | John Cash has already been on to Harold Gunson at the    |
| 8  |    | NBA so we need to do something about this very quickly," |
| 9  |    | but I can't be absolutely clear about that.              |
| 10 | Q. | You were persuaded by Dr Gillon's presentation because   |
| 11 |    | it was clear that look-back was feasible. Was that the   |
| 12 |    | main point of his presentation?                          |
| 13 | Α. | I think that was the main point but allied to that was   |
| 14 |    | a growing awareness that treatment was becoming          |
| 15 |    | available for infected patients.                         |
| 16 | Q. | Yes. So Dr Gillon's presentation covered the treatment   |
| 17 |    | aspect as well?  |
| 18 | Α. | I don't know that it did but at the back of my mind      |
| 19 |    | and you know, given the Hepatitis C conference that we   |
| 20 |    | have already discussed and Dr Dusheiko's presentation on |
| 21 |    | treatment, I mean, all of that would have been quite     |
| 22 |    | fresh in my mind. But I think the main thrust of Jack's  |
| 23 |    | presentation and why I was convinced by it was his       |
| 24 |    | demonstration of the feasibility because that had been   |
| 25 |    | one of the major arguments against proceeding with       |

1 look-back up until then.

| 2  | Q. | Yes. We have seen from other references in the minutes   |
|----|----|--|
| 3  |    | that Mr Panton has previously referred to liability,     |
| 4  |    | concern about liability. Do you remember if that was     |
| 5  |    | something that featured in your discussions?             |
| 6  | Α. | On this day, when I went back to?                        |
| 7  | Q. | Yes.   |
| 8  | Α. | I don't recall that being an element of the discussion,  |
| 9  |    | no.  |
| 10 | Q. | Just trying to think about, I know it's a long time ago  |
| 11 |    | but did your thinking go: well, I know there is          |
| 12 |    | treatment, I have now been told that it's feasible to do |
| 13 |    | look-back and the implications of that are that if we    |
| 14 |    | don't do it, there may be some legal liability because   |
| 15 |    | there is a breach of duty of care? Did that part of the  |
| 16 |    | equation feature in your thinking?                       |
| 17 | A. | I can't be clear about that but I suspect it formed part |
| 18 |    | of our collective thinking, as over the next couple of   |
| 19 |    | days we put our views together and we obviously sought   |
| 20 |    | legal advice on the issue of liability. So it must have  |
| 21 |    | been an element of, if not my thinking, our collective   |
| 22 |    | discussions around that time.                            |
| 23 | Q. | Yes. So that was the sequence of events: you went to     |
| 24 |    | somebody for legal advice?                               |
| 25 | Α. | My policy colleagues would have sought that legal        |

1 advice, yes.

| 2 | Q. | On  | the   | basis | of | this | new | information | that | look-back | was |
|---|----|-----|-------|-------|----|------|-----|-------------|------|-----------|-----|
| 3 |    | fea | asibi | le?   |    |      |     |             |      |           |     |

- 4 A. Yes. And it had been demonstrated as feasible in a part5 of Scotland.
- 6 Q. Yes.
- 7 A. So that made us different from the rest of the UK.

8 Q. Yes. So who would organise obtaining that advice?

- 9 A. I imagine Rab Panton did.
- 10 Q. Right. Okay.
- 11 A. I can't be sure. I haven't seen any -- the files
- 12 relating to this period are not available in many cases.
  13 So I can't be sure.
- 14 Q. Yes. Do you know who provided that advice, if anyone?
- 15 A. I can't recall, I am afraid.
- 16 Q. No. Do you know when it was provided?
- A. Lord Fraser's letter refers to it and I spoke about it
  at MSBT, so some time between May and September we had
  obviously obtained that advice but I can't recollect how
- 20 quickly we went about it.
- 21 Q. Yes. This would be from a Scottish Office solicitor?22 A. Yes.
- 23 Q. Do you remember what the advice was? Could you describe 24 it?
- 25 A. Well, I think it's as captured in the text in

1 Lord Fraser's letter, that, having demonstrated the 2 feasibility of the look-back exercise, Scottish ministers would be vulnerable if the look-back was not 3 proceeded with across the country. 4 Q. Yes. Do you have a memory of reading the advice? 5 Not really, I am afraid. 6 Α. 7 Q. No. I'm sure I did read it but I can't recollect. 8 Α. 9 Q. Yes. Okay, thank you. So by the end of this meeting of 10 18 May, what did you think had been decided? Was it SNBTS were to wait until you had conferred with 11 12 colleagues before confirming their policy? 13 A. Yes. Q. Right. Could we have a look at [SNB0084779]? This is 14 15 a fax from Mr David McIntosh to Mr Panton. Have you seen this before? 16 17 A. Yes, I have got a copy in front of me. 18 Q. Okay. So we see that what it says is: 19 "The MSC has now formally recommended to me that 20 service should implement a look-back policy ... " 21 He says: 22 "This is sufficient grounds for immediate acceptance . . . " 23 24 And he is intending to give colleagues in England, 25 Wales and Northern Ireland, prior warning of an

| 1  |    | intention to activate look-back with effect to           |
|----|----|--|
| 2  |    | 1 June 1994. Do you remember seeing that document at     |
| 3  |    | the time?  |
| 4  | A. | No, I don't recollect seeing it at the time.             |
| 5  | Q. | No.  |
| 6  | A. | The annotations don't copy me in but colleagues probably |
| 7  |    | made me aware of it. I don't recollect seeing it at the  |
| 8  |    | time.  |
| 9  | Q. | Would you have been surprised to see that standing the   |
| 10 |    | discussions at the meeting?                              |
| 11 | A. | Yes.   |
| 12 | Q. | Yes. Okay. The next document I would like you to look    |
| 13 |    | at is [SNB0084783]. This is a letter which records       |
| 14 |    | a meeting, Professor Cash, Brian McClelland,             |
| 15 |    | Jack Gillon, at SOHHD on 24th. Do you remember that      |
| 16 |    | meeting?   |
| 17 | A. | No, I don't remember it. I imagine that we established   |
| 18 |    | it to try and work through the logistical issues around  |
| 19 |    | this matter.   |
| 20 | Q. | Yes. But you were at the meeting?                        |
| 21 | A. | I believe I was but I really have no recollection of the |
| 22 |    | discussion, I am afraid.                                 |
| 23 | Q. | Okay. I would like to jump forward to September 1994.    |
| 24 |    | Could we go to [SGH0040840]? This is a meeting about     |
| 25 |    | SNBTS general issues, Mr Tucker. He is your superior at  |
|    |    |  |

1 this point?

| 2  | A. | Not strictly speaking. He was, as far as grades were     |
|----|----|--|
| 3  |    | concerned at that point, my equivalent on the policy     |
| 4  |    | side.  |
| 5  | Q. | Yes. And so we see that he is present, Dr Keel,          |
| 6  |    | yourself, Mr Panton, Mr Wildridge.                       |
| 7  | Α. | Yes.   |
| 8  | Q. | Do you remember this meeting?                            |
| 9  | Α. | No, I am afraid not.                                     |
| 10 | Q. | Okay. Let's have a look at 0841, please. We see under    |
| 11 |    | the heading "Hepatitis C look-back":                     |
| 12 |    | "Glasgow Royal Infirmary had written seeking funding     |
| 13 |    | for the costs of treatment with Alpha interferon for     |
| 14 |    | patients with transfusion acquired Hepatitis C and       |
| 15 |    | pharmaceutical services had replied to the effect that   |
| 16 |    | whoever was in charge of clinical care was also in       |
| 17 |    | charge of prescribing. The position of the department    |
| 18 |    | was that the source of the infection was, in this case,  |
| 19 |    | irrelevant and that no additional funding would be made  |
| 20 |    | available."  |
| 21 |    | If we go over the page, at the top, again in the         |
| 22 |    | context of look-back:                                    |
| 23 |    | "Dr Keel had attended a meeting of hepatologists and     |
| 24 |    | their view was that a look-back was necessary as part of |
| 25 |    | a general duty of care. It was noted that SNBTS had      |
|    |    |  |

1 still not produced suitably detailed papers on the costs 2 and consequences of a look-back but that in any case the issue was now being taken forward by ... " 3 Should that be "not being taken forward" or "now 4 being taken forward," do you think? 5 A. I imagine it's "now". 6 7 Q. Okay: 8 "... the department would continue to monitor the 9 situation." 10 So at this stage, Dr Keel, what is the plan about look-back as far as SHHD is concerned? 11 12 I think there was general agreement that it should go Α. 13 ahead. 14 Q. Yes. 15 The meeting of hepatologists, I don't recall, but what Α. 16 I have said reflects my own view that the look-back had 17 to proceed because this was part of a duty of care that SNBTS had to their donors and recipients. 18 19 Q. Yes. Had any discussions taken place with the 20 Department of Health colleagues about look-back by this 21 stage? 22 I imagine they would have but I can't remember what the Α. 23 substance would be other than sharing with them the 24 evidence that SNBTS had demonstrated that look-back was 25 feasible, our view in SHHD that it should therefore go

1 ahead and our desire for it to be discussed in MSBT, in 2 particular, so that a collective view could be taken 3 across the UK about proceeding. Q. Yes. Okay. Could we go to [SNB0099176], please? These 4 are the minutes of the MSC for 9 and 10 November and 5 6 again, do you think you have been specifically invited 7 along to discuss look-back? 8 No, I have no recollection of a specific invitation. Α. 9 Ο. Okay. If we could go to 9185, we see at the bottom of 10 the page under "New Items": 11 "look-back: HCV": 12 "After a full discussion in which the principles of 13 look-back of HCV PCR positive donor archive samples and 14 appropriate communication with recipient's GPs were 15 agreed, it was felt that the position concerning PFC 16 products required further consideration. The committee 17 felt it would be inappropriate to make a policy decision 18 at this time and that further discussion was required. "DB McClelland to circulate look-back information 19 20 . . . " 21 That was back in 1993. So do you have 22 a recollection of having that information circulated to 23 you? 24 A. No, I have no recollection of having information 25 circulated by Brian McClelland and I suppose that's why

1 the subsequent MSC meeting in May, Jack Gillon's 2 presentation, came as a revelation because I had nothing 3 written down about the look-back and, you know, the discussion here, it comes half way through a very, very 4 lengthy meeting, minuted on page 10 of 18. It doesn't 5 6 convey to me that SNBTS were attaching a great deal of 7 priority to this, amongst all the other issues that they were discussing on that day, but I certainly don't 8 9 recollect receiving any written information about the 10 pilot exercise. I'm sure I would have remembered that. Thank you. Could we go to October 1994 now? 11 Q. 12 [SGH0040803]. 13 This is another general issues meeting at which you are in attendance with Mr Tucker, Mr Panton and also 14 15 members of the Common Services Agency. If we could go 16 to 0805, this is about Hepatitis C look-back: 17 "Mr Tucker advised that the MSBT was examining proposals for a look-back and was returning to the 18 19 subject in December." 20 So it looks as though you are waiting for a decision 21 from the Advisory Committee? 22 A. Yes. 23 Then it's recorded: Q. 24 "Dr Keel and Dr Perry awaited the decision but 25 pointed out that MSBT had no real locus in this since it

1

was not a matter of blood safety."

2 Could you just explain what's recorded there,
3 Dr Keel?

Yes, I think actually with hindsight it's a kind of 4 Α. nitpicking point on my and Bob Perry's part, and 5 6 probably not terribly material to any of the discussions 7 that were going on. But in strict terms the committee 8 is about the microbiological safety of blood for 9 transfusion; it's not about tracing recipients of blood 10 transfusion; it's about ensuring that the blood supply is safe before it's issued. 11

But, I mean, whether -- I can't remember the discussion but it seems to me a rather immaterial point that I was making, quite frankly.

Q. That doesn't represent a change of view at SHHD that meant that you didn't have to, if you like, pay too much attention to what the Advisory Committee was telling you about look-back?

19 A. Well, I think that the view in SHHD was very much 20 coloured by what had happened locally in Southeast 21 Scotland. That's point number 1. And it may have been 22 that by then we had the legal advice to which we have 23 referred. So that's, I suppose, what's to the forefront 24 of our minds when we were having these discussions. So 25 the idea that a committee -- MSBT -- even though it was

set up as a UK Advisory Committee, might step in and
 decline to implement this policy, I suppose -- well, it
 would have been undesirable from a Scottish perspective.
 I think both in SHHD and in SNBTS.

5 Q. Yes.

6 PROFESSOR JAMES: Could I just ask you: were you by this7 time attending the meetings of the MSBT?

8 A. Yes, I was.

9 PROFESSOR JAMES: You mentioned earlier that it was your 10 recollection that it was Professor Zuckerman who had 11 said that in his view, interferon treatment was really 12 not likely to be very helpful in the treatment of 13 Hepatitis C.

14 You may well have the minutes of those two meetings 15 here but reconstructing events, do you believe that this may have been a sort of delaying tactic to take 16 17 Professor Zuckerman's point and say, "Oh, well, we will 18 have to come back to that, so we will delay making 19 a decision about this issue for another three months until another meeting"? Is that the impression you are 20 21 trying to give us?

A. No, that's not the impression I'm trying to give. My recollection of discussions in MSBT were that the main factor in influencing their view was the demonstration of the feasibility of undertaking the exercise. The

1 issue of effectiveness of treatment was a secondary one 2 and I think even at that point there was recognition 3 that Alpha interferon was only the first of what were likely to be many forms of effective treatment, and it 4 was recognised, notwithstanding Professor Zuckerman's 5 views, that it was effective in a number of patients. 6 7 So I don't think that MSBT were trying to stall because of what Harry Zuckerman said. 8

9 PROFESSOR JAMES: I'm very pleased to hear it, thank you. 10 MR GARDINER: We can look at the minutes for December 1994 at [SNB0084820]. Before we do, I just want to ask you, 11 12 Dr Keel: one gets the impression reading the documents 13 that having come very close to making the decision about 14 going ahead with look-back at the previous meeting, 15 after the presentation from Dr Gillon, things are starting to get delayed, and one gets the impression 16 17 that the urgency is starting to go out of the question. 18 Is that the wrong impression?

19 A. I think it is the wrong impression because even if we 20 had been in a position in Scotland to unilaterally say 21 there is going to be a look-back across the whole 22 country, the day after that meeting on 18 May, other 23 bits of the country would have had to do the kind of 24 preparatory and planning work that Southeast Scotland 25 had undertaken over a period of many months. In fact it

1 may have run on for years. I can't really remember the 2 detail.

3 So there was a desire that we should proceed on a UK 4 basis in this and in other blood transfusion-related 5 matters. That was always a recurring theme and a focus 6 for us.

7 So if we were slightly ahead of the game in 8 Scotland, having done this pilot exercise, and there was 9 a bit more awareness in Scotland of what might be 10 required in terms of undertaking it, the rest of the UK were not as up to speed even as we were. So there 11 12 needed to be a lot of planning and advance warning of 13 the blood transfusion services in other parts of the UK 14 before they could have possibly undertaken it.

15 Q. Was the situation south of the border holding you up at 16 this point?

17 A. I don't think at this point but clearly Lord Fraser
18 indicated in his letter to Tom Sackville that, because
19 we had demonstrated the feasibility in Scotland of doing
20 look-back, he felt, based on the advice he had received,
21 that we needed to get on with it.

Q. I should have said what I meant by "at this point" because, you see, these minutes are 15 December 1994 and Lord Fraser's letter is 22 December 1994. So it's very close.

1 A. Yes.

| 2  | Q. | But let's have a look at them. On the first page we see  |  |  |  |  |  |  |
|----|----|--|--|--|--|--|--|--|
| 3  |    | who is there: Dr Mitchell, Dr Mortimer, Dr Perry, you    |  |  |  |  |  |  |
| 4  |    | are there as an observer. This is, as I said,            |  |  |  |  |  |  |
| 5  |    | 15 December 1994. If we could go to 4824, under the      |  |  |  |  |  |  |
| 6  |    | heading of "HCV look-back", it starts at paragraph 7.1,  |  |  |  |  |  |  |
| 7  |    | and just to get an overview, if we could go over the     |  |  |  |  |  |  |
| 8  |    | page, paragraph 7.4, 7.5, 7.6, 7.7 all look-back. Then   |  |  |  |  |  |  |
| 9  |    | over the page, 7.8, 7.9, 7.10, 7.11, 7.12. Over the      |  |  |  |  |  |  |
| 10 |    | page, please, there are three pages of notes about       |  |  |  |  |  |  |
| 11 |    | look-back.   |  |  |  |  |  |  |
| 12 |    | So was the discussion about look-back particularly       |  |  |  |  |  |  |
| 13 |    | extensive at this meeting?                               |  |  |  |  |  |  |
| 14 | Α. | Clearly it was, yes.                                     |  |  |  |  |  |  |
| 15 | Q. | Yes. Do you remember how long you talked about it for?   |  |  |  |  |  |  |
| 16 | Α. | No, I can't tell how long.                               |  |  |  |  |  |  |
| 17 | Q. | An hour? More than an hour?                              |  |  |  |  |  |  |
| 18 | Α. | I honestly can't remember. I would imagine an hour       |  |  |  |  |  |  |
| 19 |    | would be a reasonable guesstimate of how long we spent   |  |  |  |  |  |  |
| 20 |    | on it.   |  |  |  |  |  |  |
| 21 | Q. | What was the mood of the meeting? Were there forthright  |  |  |  |  |  |  |
| 22 |    | views expressed?   |  |  |  |  |  |  |
| 23 | Α. | I infer from the earlier paragraphs that MSBT had set up |  |  |  |  |  |  |
| 24 |    | a subgroup. I imagine to think about the logistical      |  |  |  |  |  |  |
| 25 |    | difficulties this might present to England in            |  |  |  |  |  |  |

1 particular.

| 2  | Q. | I was just wondering what you could remember of the    |
|----|----|--|
| 3  |    | meeting in terms of                                    |
| 4  | A. | I think a lot of it the discussion was therefore       |
| 5  |    | based on next steps, you know, in practical terms.     |
| 6  |    | I think what I read from the minutes and what I can    |
| 7  |    | remember, which is not very clear, is that we were     |
| 8  |    | moving forward on a UK basis, very much so at this     |
| 9  |    | point.   |
| 10 | Q. | Yes. Could we go to 4825? If you look at               |
| 11 |    | paragraph 7.6:   |
| 12 |    | "Dr Robertson said that four writs had been issued     |
| 13 |    | against the NBA and its legal advice was that the duty |
| 14 |    | of care existed in this case."                         |
| 15 |    | Then at the bottom of the page, paragraph 7.7:         |
| 16 |    | "Professor Zuckerman, sharing the view of              |
| 17 |    | Dr Mortimer, that the question of look-back was driven |
| 18 |    | by lawyers."   |
| 19 |    | Then if you could go over the page, at 7.10, it        |
| 20 |    | records one of your contributions:                     |
| 21 |    | "Dr Keel said that the view in Scotland was that the   |
| 22 |    | Secretary of State was vulnerable as look-back was     |
| 23 |    | feasible since donors could be identified and traced,  |
| 24 |    | and advice from Scottish Office lawyers was that       |
| 25 |    | look-back should start immediately."                   |
|    |    |  |

1 I'm just wondering whether what you were referring 2 to there as the Secretary of State being vulnerable, was that vulnerable to actions of negligence? Is that what 3 you are referring to there? 4 A. Yes, in not proceeding with a look-back that had been 5 demonstrated to be feasible in a part of Scotland. 6 7 Q. Yes. I'm just wondering how important the concern about 8 the liability was in reaching the decision? 9 Α. Well, it was a material issue. There is no doubt about 10 it, because once you have got legal advice of that nature, you have to take that seriously. But it wasn't 11 12 there at the beginning, the outset, as far as I can 13 recall, as a substantive issue, as the most important 14 issue that needed to be taken into account in deciding 15 whether the policy should proceed as it has proceeded. Q. So it would be wrong to think that that was the main 16 17 determining factor in the decision? 18 Α. I think so. Okay. If we go down to the bottom of the page, we see 19 Q. 20 the conclusion: 21 "In the committee's view there is a duty of care 22 towards those infected with HCV as a result of NHS 23 treatment. It follows that procedures should be put in 24 place to identify those patients at risk. 25 "Whatever is done should be done equally and

1 uniformly throughout the UK."

2 Over the page, please:

3 "Guidance should be drawn up as soon as possible on 4 procedures for identifying those at risk and ..."

7.13:

5

6 "The committee agreed that these conclusions would 7 be passed on to the Secretaries of State of all four 8 health departments."

9 Dr Keel, when you left that meeting, what was your 10 impression about what was likely to happen next as far 11 as UK-wide look-back was concerned?

12 A. That the various bits of the UK, the health departments, 13 would advise their ministers separately that look-back 14 should be undertaken across the UK and informing 15 ministers that the detail was being worked on by various 16 groups and that this would be based on the results from 17 the Southeast Scotland pilot.

18 Q. So what was your impression about how quickly a decision 19 would be made about that?

A. It's difficult to recollect at this length of time after the event but I think that my impression would have been that we were going to get on with this pretty quickly -well, as soon as the blood transfusion services could get the guidance developed and then in place in the different parts of the UK. That would be a plan and it 1 would be progressed quickly.

| 2  | Q. | Yes. If we could go to [SNB0084847]. So the meeting      |
|----|----|--|
| 3  |    | that you went to was on 15 December. A week later.       |
| 4  |    | This is Mr Tucker sending a copy of Lord Fraser's letter |
| 5  |    | to David McIntosh. Lord Fraser's letter was dated        |
| 6  |    | 22 December 1994. Can you remember what happened at      |
| 7  |    | SHHD between 15 December and 22 December?                |
| 8  | Α. | No, I can't. I mean, I can speculate, if that would be   |
| 9  |    | helpful?   |
| 10 | Q. | I think that would be.                                   |
| 11 | A. | I would have come back from MSBT and briefed colleagues. |
| 12 |    | Probably I would have done a note of the meeting, that   |
| 13 |    | was my usual habit, and noted that I had suggested that  |
| 14 |    | our ministers were vulnerable because of the legal       |
| 15 |    | advice that we had received. I can't recollect whether   |
| 16 |    | I met with colleagues I suspect I probably did to        |
| 17 |    | discuss getting on with this from a Scottish point of    |
| 18 |    | view. And I suspect there was a collective view that we  |
| 19 |    | needed to inject a degree of urgency into this; hence    |
| 20 |    | the letter from Lord Fraser to Tom Sackville.            |
| 21 | Q. | Yes. I mean, that is notwithstanding your impression at  |
| 22 |    | that meeting that things were going to progress fairly   |
| 23 |    | quickly at a UK level?                                   |
| 24 | Α. | Well, the minutes suggest that there is a lot of         |
| 25 |    | activity underway, that a group had been set up, that    |

1 they were talking about developing algorithms and 2 quidelines for clinicians who were going to be in 3 contact with patients. So the minutes give an impression, at least to me, of activity but I don't know 4 whether there were other impressions, reading between 5 6 the lines, that I brought back to Scotland, which 7 suggested that perhaps things were not going to move as 8 quickly as we might have desired. I honestly cannot 9 recollect.

Q. But putting it all together, that seems the most likely scenario, does it not, that you have formed the impression one way or the other that things aren't going to move as quickly as SHHD would like?

14 Well, given our different position and in view of the Α. 15 legal advice that we had, clearly there was more 16 pressure on Scotland to move forward here than might 17 have been felt in the other parts of the UK. But allied 18 to that was the fact, as I have already said, that we 19 had some practical experience of running the look-back, 20 even if it was only in part of Scotland. The rest of 21 the UK didn't have that. They were coming new to it. 22 And, you know, England is a much bigger country than 23 Scotland for a start. So the scale of the look-back 24 exercise and all the multifarious strands and hurdles 25 that it encountered were always going to be greater

1 there. So I don't think we should underestimate the 2 task that the blood transfusion services, particularly in the other parts of the UK, were being asked to 3 undertake. 4 Q. Yes. Thank you. Just to clarify a point, I would like 5 to go back to the statement that you gave us. Could we 6 7 have a look at page 3 of [PEN0180396]. This is the statement that you gave us, isn't it? 8 9 Α. Yes, it is. And you have answered in your evidence most of the 10 Ο. questions that you have covered in your statement but 11 12 there is just one thing I would like to ask you about 13 here. The question number 5 is: 14 "Dr Keel said that the view in Scotland was that the 15 Secretary of State was vulnerable as look-back was feasible since donors could be identified and traced and 16 17 advice from Scottish Office lawyers was that look-back 18 should start immediately. Please explain this comment in more detail." 19 20 You say: 21 "I was quoting the advice received from the 22 solicitor's office and do not either have a copy or 23 a clear recollection of the precise terms of the advice. 24 However, I think that the legal advice would have been 25 based on the fact that the SEBTS pilot project had

1 demonstrated the feasibility of conducting a look-back 2 exercise and therefore the position in Scotland was different from the position in England ...." 3 I think that's what you have told us earlier today? 4 5 Α. Yes. Then you say: 6 Q. 7 "We could no longer argue that it would not be feasible to conduct the exercise in Scotland." 8 9 What I wanted to ask you, Dr Keel, is why would you 10 be wanting to argue that position? Why would your inclination be that way? Why would you be looking for 11 12 arguments? 13 Well, I was reflecting the previous argument that had Α. 14 been deployed, not necessarily a desire to redeploy it 15 in this new situation. We had argued, or Government had 16 argued from the introduction of Hepatitis C testing that 17 a look-back exercise should not be undertaken, mainly 18 for reasons of logistics and the perception that it 19 would not be feasible. The world had moved on by the 20 time of the Southeast Scotland pilot, which demonstrated 21 the feasibility. So that argument, that it wasn't 22 feasible, could no longer be deployed. 23 What I'm getting at is were you making that argument Q. 24 because that was the position or were you deploying it

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as an argument because your inclination was not to start

1 look-back for some other reason? I'm really focus --2 No, no, no, I hope I made it clear in my earlier Α. evidence that, having heard Jack Gillon present, I was 3 absolutely convinced that proceeding with look-back was 4 the right thing to do for a whole raft of reasons. 5 I'm talking about before that. 6 Ο. 7 Α. I suppose I share the collective mindset of the time, 8 that the look-back would not be feasible, that 9 logistically it would be impossible to conduct 10 a look-back. Yes. Okay. Thank you. Question 7. I'm nearly 11 Q. 12 finished: 13 "What steps, if any, did the SHHD take to draw doctors' attention to the availability of testing and 14 15 implications of HCV for patients before April 1995?" 16 You say: 17 "It is not normal practice to issue circular letters 18 to the whole profession in relation to new tests. The 19 introduction of new diagnostic tests is a fairly regular 20 occurrence; hepatologists would have been aware of the 21 availability of the Hepatitis C test as a diagnostic 22 tool and introduction of HCV testing would not have been 23 treated differently from any other diagnostic test." 24 I'm just wondering if there is an analogy that we 25 can draw with HIV. The Inquiry has heard about booklets

1 that were sent to doctors when HIV testing came in.
2 Perhaps I could just show you a letter about that,
3 [SGH0027079]. You won't have seen this before.
4 A. No.

5 Q. So just take your time and read it. (Pause)

So this is 1 October 1985, the Chief Medical Officer 6 7 is asking for a booklet to be sent to all doctors and that's at the time of introduction of a test for 8 9 HTLV-III, later called HIV. If you could have a look at 10 [SGH0027081], that's a booklet that was sent out. Τf you look over the page, it talks about introduction of 11 12 the screening test. Further down this page "Procedure" 13 and if we could go over the page, "Interpretation of results". 14

15 I'm not going to take up more time with this 16 booklet, but would you accept, Dr Keel, that what was 17 being suggested in the question has been done before? 18 A. Well, clearly it has but I would suggest that the 19 situation around the discovery of the AIDS virus and the 20 context in which this booklet was issued are radically 21 different from that in relation to the Hepatitis C 22 virus. I mean, I can remember, as a clinician, these 23 viruses being discovered and the growing awareness of 24 the devastating consequences of being infected with that 25 virus, and of course it was many, many years before

there was anything like effective treatment to deal with AIDS. There was enormous lack of awareness and great fear of the virus within the general population and I suspect that the decision to issue this guidance was as a result of that lack of awareness of this new, very, very strange and worrying virological entity.

7 As I say, the situation with Hepatitis C was by no 8 means the same. For example, up until, one might say, 9 the late 80s/early 90s, there was still a widespread 10 view that non-A non-B Hepatitis, later to be defined as Hepatitis C, was a fairly benign virus, which did not 11 12 have many adverse effects on individuals' health. 13 Absolutely the opposite from HTLV-III/HIV. So I think we are talking about two very different situations here. 14 15 Would you accept that it could have been done? Ο. What could have been done? 16 Α. 17 Ο. A booklet, which explained about the new test and the 18 implications and so on. 19 Well, certainly the guidance that went out on the Α.

look-back contained a great deal of detailed information
for general practitioners and other doctors on the test,
the implications of a positive test, the management of
patients with the virus. So I suppose one might argue
that that was guidance of a sort, mirroring this.
I'm suggesting that that could have been done earlier,

- 1 maybe September 1991.
- 2 With what end in view? Α.

Well, information to medical practitioners about the new 3 Ο. 4 test.

A. But as I said in my statement, the advent of this new 5 test was not perceived as being different from any other 6 7 virus and other types of blood test that come along daily. The Chief Medical Officer would never be done 8 9 writing out to doctors if we had adopted that as 10 a general principle. Which I think reinforces what I said earlier about AIDS being a very, very different 11 12 scenario.

13 I have just got two more questions, Dr Keel, and the Q. 14 second last one is a very general question. I would 15 like to ask you to answer this question based on your considerable experience of the Medical Civil Service. 16

17 At the beginning of your evidence this afternoon you 18 described the MSBT and by implication its predecessor, 19 the ACVSB, as the principal UK Advisory Committee and as 20 being run out of the Department of Health. You said it 21 was the committee that the health departments 22 collectively looked to for advice and later you 23 described it as the vehicle of the government health departments. 24

25

I just wondered if that isn't a bit circular because

| 1 | it sounds like it's the department advising the |
|---|---|
| 2 | department effectively?                         |

Well, certainly the Deputy Chief Medical Officer at that 3 Α. point chaired that Advisory Committee. That is no 4 longer the case. Its equivalent is chaired by an 5 6 independent expert clinician. But round that table, 7 under the chairmanship of the DCMO, were a wide range of 8 experts: virologists, clinicians from other backgrounds, 9 haematologists, blood transfusion experts. I certainly 10 think that the Department of Health, as well as the other UK health departments, placed great store on that 11 12 independent expert advice, which formed the collective 13 view coming from that committee.

14 Q. Yes.

15 A. So I wouldn't accept that it was the department advising16 the department.

Q. Right. Okay. And my last question. Could we have a look, please, at [PEN0181410]? This isn't a very good copy and you won't have seen this before. It's a letter to Roseanna Cunningham to the Minister for Health and Community Care, Andy Kerr MSP. Do you remember seeing this?

A. No, but I probably did see it but I don't recollect it,I am afraid.

25 Q. Just to get some context, we see it's 16 June 2006 and

it's a letter to Roseanna Cunningham as the convener of
 the health committee of the Scottish Parliament.
 A. Yes.

4 Q. It says:

5 "Dear Roseanna, I'm writing in response to your 6 letter of 19 April on the decision of the health 7 committee to call for a full judicial inquiry into 8 infection with Hepatitis C through NHS treatment with 9 a particular focus on the efficacy of the look-back 10 exercise."

11 If we go down to the bottom of the page, under the 12 heading of "Look-back exercise":

"Concerns have been expressed by the committee that some patients did not know for long periods that they had been infected with Hepatitis C, in particular through blood transfusions, and that there should have been a more thorough and comprehensive strategy for tracing and counselling patients."

19 If could we go over the page:

"As my earlier letter explained, a UK look-back
exercise was started in 1995 to trace as many patients
as possible who had contracted Hepatitis C through blood
transfusions. This exercise was agreed by UK ministers
on the basis of medical and scientific advice, and the
different options for carrying out the look-back were

1 carefully considered. I set out below the detail of how 2 the look-back exercise was developed and the basis for 3 the decisions taken."

4 It's the next few lines that I would like you to 5 concentrate on:

6 "These were decisions taken by the UK Government, 7 based on advice from the relevant professional Advisory 8 Committees, before devolution. I do not think that 9 there can be any strong basis for seeking to reopen 10 these issues and revisit these decisions now, ten years 11 later."

12 Dr Keel, I just wanted to ask you to agree with me 13 that that is not a correct statement of the position, is 14 it?

15 A. Which particular part is it?

16 Q. "These were decisions taken by the UK Government based 17 on advice from the relevant professional Advisory 18 Committees."

19 A. Well, the look-back proceeded on a UK basis -- was

20 a decision for UK Government, informed by the evidence 21 that Scotland had presented to it.

22 Q. Was it not a decision taken by Lord Fraser in the letter 23 of 22 December?

24 A. Well --

25 Q. 1994.

1 A. I think if we hypothesise and if the Department of 2 Health had decided against proceeding with the look-back exercise, I suspect that Lord Fraser would have wanted 3 to proceed in Scotland. So if that answers your 4 question, then, I believe that would have been the case. 5 Q. Well, what I'm getting at is that he made the decision, 6 7 the Scottish Office made the decision, not the UK 8 Government. Was that not right? 9 A. Well, for Scotland, yes, but we didn't make the decision 10 for the UK. Q. For Scotland? Indeed. 11 12 A. Yes, but we didn't go ahead on a Scotland-only basis; it 13 was a UK look-back exercise. As I said, things might 14 have been different had DH decided not to proceed. But, 15 as it turned out, the whole of the UK went ahead with it, based on Scottish experience. 16 17 O. Hm-mm. 18 A. And I think the views in the Department of Health would 19 have been very strongly informed by what we were saying 20 in Scotland was possible. 21 Q. Would you not agree that the decision to go ahead with 22 look-back was taken by Lord Fraser? 23 A. For Scotland, yes. 24 Q. Indeed, for Scotland. 25 A. Yes.

1 Q. Would you agree with that? 2 A. I would agree. Q. Thank you. Thank you very much, Dr Keel. 3 THE CHAIRMAN: Mr Di Rollo? 4 MR DI ROLLO: No, thank you, sir. 5 THE CHAIRMAN: Mr Anderson? 6 7 MR ANDERSON: Thank you, sir, I have no questions. THE CHAIRMAN: Mr Sheldon? 8 9 Questions by MR SHELDON 10 MR SHELDON: Just a couple of matters of detail, if I may. 11 Dr Keel, we heard some evidence about the symposium 12 on HCV in October of 1993, I just wanted to ask you how 13 you came to be there? A. I have no clear recollection but I imagine I received 14 15 a flyer, as I very often do for conferences, at what is my local college and decided that this would be of 16 17 interest and applied to go to it. Q. All right. You weren't specially invited to it or 18 19 something of that sort? A. No, certainly not. 20 21 All right. The only other matter I wanted to ask you Ο. 22 about was about the MSC committee meeting of 18 May, which we have heard about in some detail. I think it 23 24 would be fair to say that there was a fairly lengthy and detailed discussion of look-back at that meeting. Is 25

- 1 that correct?
- 2 A. Yes.

| 3 | Q. | Do you | recall  | whether  | look-back | was | an | item | on | the |
|---|----|--------|---------|----------|-----------|-----|----|------|----|-----|
| 4 |    | agenda | for tha | t meetir | ng?       |     |    |      |    |     |

5 A. My recollection from the minutes -- and having revisited
6 them recently, I was rather surprised to see that

- 7 look-back was under any other business rather than
- 8 a substantive agenda item.
- 9 Q. Can you help us then whether there was any mention of 10 look-back per se on the agenda that was issued prior to 11 the meeting?
- 12 A. I can't remember, I am afraid.
- 13 Q. All right. Thank you.
- 14 I have nothing else, sir.
- 15 THE CHAIRMAN: Dr Keel, thank you very much. We are asking 16 you to dredge your memory, I appreciate, but we are
- 17 grateful for all the help you have given.
- 18 A. Thank you.
- 19 MR GARDINER: Sir, there are no more witnesses today.
- 20 THE CHAIRMAN: Until tomorrow.
- 21 (4.25 pm)
- 22 (The Inquiry adjourned until 9.30 am the following day) 23 24
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